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# **Rules and Regulations**

#### Federal Register

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

### **DEPARTMENT OF TRANSPORTATION**

#### **Federal Aviation Administration**

#### 14 CFR Part 39

[Docket No. FAA-2015-0165; Directorate Identifier 2015-NE-02-AD; Amendment 39-18212; AD 2015-15-03]

### RIN 2120-AA64

# Airworthiness Directives; General Electric Company Turbofan Engines

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** We are adopting a new airworthiness directive (AD) for all General Electric Company (GE) GEnx turbofan engine models. This AD was prompted by reports of GEnx-1B and GEnx-2B engines experiencing power loss in ice crystal icing (ICI) conditions. This AD precludes the use of full authority digital engine control (FADEC) software, version B175 or earlier, in GEnx-1B engines, and the use of FADEC software, version C065 or earlier, in GEnx-2B engines. We are issuing this AD to prevent engine failure, loss of thrust control, and damage to the airplane.

**DATES:** This AD is effective August 24, 2015.

ADDRESSES: For service information identified in this AD, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: geae.aoc@ge.com. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7125.

## **Examining the AD Docket**

You may examine the AD docket on the Internet at http:// www.regulations.gov by searching for and locating Docket No. FAA-2015-0165; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800-647-5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

### FOR FURTHER INFORMATION CONTACT:

Christopher McGuire, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7120; fax: 781–238–7199; email: chris.mcguire@faa.gov.

# SUPPLEMENTARY INFORMATION:

# Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all General Electric Company (GE) GEnx turbofan engine models. The NPRM published in the **Federal** Register on March 17, 2015 (80 FR 13797). The NPRM was prompted by reports of GEnx-1B and GEnx-2B engines experiencing power loss in ICI conditions. The NPRM proposed to preclude the use of FADEC software, version B175 or earlier, in GEnx-1B engines, and the use of FADEC software, version C065 or earlier, in GEnx-2B engines. We are issuing this AD to correct the unsafe condition on these products.

# Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA's response to each comment.

### Request To Delay Issuance of AD

United Airlines (United) commented that this AD should not be issued until after GEnx-1B FADEC software version B185 is released. United noted that software version B185 will provide a greater level of protection from damage to the engine due to ice crystal icing. United indicated that the proposed AD would allow engines to operate with FADEC software versions B178 and B180, which do not provide the protection of software version B185.

We do not agree. We find that precluding use of FADEC software version B175 or earlier provides an adequate level of safety for inadvertent encounters in ICI environments. We did not change this AD.

# Request To Withdraw AD and Supersede Another AD

United requested that we withdraw the proposed rule and, instead supersede AD 2013–24–01 (78 FR 70851, November 27, 2013), which requires revising the airplane flight manual for Model 747–8 and 747–8F series airplanes and Model 787–8 airplanes powered by GEnx engines.

We do not agree. Our AD addresses the susceptibility of GEnx engines when operating inadvertently in ICI conditions. AD 2013–24–01 (78 FR 70851, November 27, 2013) is setting operational limitations on Boeing Model 747–8, 747–8F, and 787–8 airplanes equipped with GEnx engines. The ADs have different purposes, and superseding AD 2013–24–01 is outside the scope of this AD. We did not withdraw this AD.

# Support for the NPRM

The Boeing Company and the General Electric Company expressed support for the proposed rule.

#### Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD as proposed.

### **Costs of Compliance**

We estimate that this AD affects 80 engines installed on airplanes of U.S. registry. We also estimate that it will take about 1 hour per engine to comply with this AD. The average labor rate is \$85 per hour. No parts are required. Based on these figures, we estimate the total cost of the AD to U.S. operators to be \$6.800.

#### **Authority for This Rulemaking**

Title 49 of the United States Code specifies the FAA's authority to issue

rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

# Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

# List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

# PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

### 2015-15-03 General Electric Company:

Amendment 39–18212; Docket No. FAA–2015–0165; Directorate Identifier 2015–NE–02–AD.

#### (a) Effective Date

This AD is effective August 24, 2015.

### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to all General Electric Company (GE) GEnx–1B model turbofan engines with full authority digital engine control (FADEC) software version B175 or earlier, installed, and GEnx–2B model turbofan engines with FADEC software version C065 or earlier, installed.

#### (d) Unsafe Condition

This AD was prompted by reports of GEnx–1B and GEnx–2B engines experiencing power loss in ice crystal icing (ICI) conditions. We are issuing this AD to prevent engine failure, loss of thrust control, and damage to the airplane.

#### (e) Compliance

Comply with this AD within the compliance times specified, unless already done.

- (1) Thirty days after the effective date of this AD, do not operate any GE GEnx-1B engine with FADEC software version B175 or earlier, installed in the electronic engine control (EEC).
- (2) Thirty days after the effective date of this AD, do not operate any GE GEnx–2B engine with FADEC software version C065 or earlier, installed in the EEC.

# (f) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs to this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: ANE-AD-AMOC@faa.gov.

### (g) Related Information

(1) For more information about this AD, contact Christopher McGuire, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7120; fax: 781–238–7199; email: chris.mcguire@faa.gov.

(2) GE GEnx-1B Service Bulletin (SB) No. 73-0036 R00, dated January 6, 2015, and GE GEnx-2B SB No. 73-0035 R00, dated September 16, 2014, which are not incorporated by reference in this AD, can be obtained from GE using the contact information in paragraph (g)(3) of this AD.

- (3) For service information identified in this proposed AD, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: geae.aoc@ge.com.
- (4) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

# (h) Material Incorporated by Reference

None

Issued in Burlington, Massachusetts, on July 13, 2015.

#### Carlos A. Pestana,

Acting Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2015-17703 Filed 7-17-15; 8:45 am]

BILLING CODE 4910-13-P

#### **DEPARTMENT OF TRANSPORTATION**

#### **Federal Aviation Administration**

### 14 CFR Part 71

[Docket No. FAA-2015-2219; Airspace Docket No. 15-AWA-5]

RIN 2120-AA66

# Amendment of Class B Airspace; New Orleans, LA

**SUMMARY:** This action amends Class B

**AGENCY:** Federal Aviation Administration (FAA), DOT. **ACTION:** Final rule, technical amendment.

airspace at the Louis Armstrong New Orleans International Airport, New Orleans, LA, by removing reference to the Instrument Landing System (ILS) Runway 10 Outer Compass Locator (LOM) from the text header information and surface area (Area A) description and replacing it in the Area A description with the geographic latitude/longitude coordinates of the LOM. This change is necessary due to the planned decommissioning of the LOM navigation aid. The Louis Armstrong New Orleans International Airport and New Orleans Naval Air Station Joint Reserve Base (Alvin Callender Field) airport names and airport reference point (ARP) geographic coordinates are also updated. The St. Charles and Lakefront airports, used in the Class B description, are added in the legal description text header information, as well as, the Harvey VHF Omnidirectional Range/Tactical Air Navigation (VORTAC) navigation aid. Lastly, general editing of the legal description is accomplished to improve clarity. These changes are editorial only to match existing FAA aeronautical database information and do not alter the current charted boundaries or altitudes or the ATC procedures for the New Orleans Class B airspace area. **DATES:** Effective Date: 0901 UTC,

November 12, 2015. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual

revision of FAA Order 7400.9 and publication of conforming amendments. **ADDRESSES:** FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at <a href="http://www.faa.gov/air\_traffic/publications/">http://www.faa.gov/air\_traffic/publications/</a>. The Order is also available for inspection at the National Archives and Records Administration (NARA). For

Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to http://www.archives.gov/federal\_register/code\_of\_federal-regulations/ibr\_locations.html.

FAA Order 7400.9, Airspace

PAA Order 7400.9, Airspace
Designations and Reporting Points, is
published yearly and effective on
September 15. For further information,
you can contact the Airspace Policy and
Regulations Group, Federal Aviation
Administration, 800 Independence
Avenue SW., Washington, DC 20591;
telephone: (202) 267–8783.

# FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy and Regulations Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591;

telephone: (202) 267–8783.

# SUPPLEMENTARY INFORMATION:

#### **Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the Class B airspace at the Louis Armstrong New Orleans International Airport, New Orleans, LA.

#### History

The New Orleans Class B airspace area was established as a Terminal Control Area (TCA) on July 17, 1975 (40 FR 20269, May 9, 1975). In 1993, as part of the Airspace Reclassification Final Rule (56 FR 65638, December 17, 1991), the term "terminal control area" was replace by "Class B airspace area." Because there was no VHF Omnidirectional Range (VOR) navigation aid located on the Louis Armstrong New Orleans International

Airport (formerly New Orleans International Airport-Moisant Field), the Class B airspace area was designed using the ARP latitude/longitude coordinates as the center point. When established, the surface area (Area A) included an extension, described using an arc around the ILS Runway 10 LOM. In October 2015, the ILS Runway 10 LOM is being decommissioned because it cannot be cost-effectively maintained any longer. To retain the existing charted boundaries of the New Orleans Class B airspace surface area, the FAA is using the geographic latitude/ longitude coordinates of the ILS Runway 10 LOM being decommissioned to describe the Class B airspace Area A extension. All references to the LOM in the New Orleans Class B airspace description are being removed and reference to the LOM in the Area A description is being replaced by a point using the geographic latitude/longitude coordinates of the ILS Runway 10 LOM.

In preparation of updating the New Orleans Class B airspace description, the FAA reviewed the aeronautical database and determined that the New Orleans International Airport-Moisant Field name had changed to the Louis Armstrong New Orleans International Airport, the NAS New Orleans-Alvin Callender Field name had changed to the New Orleans Naval Air Station Joint Reserve Base (Alvin Callender Field), and the respective ARP geographic coordinates for both had also changed. Further, the Class B airspace area legal description used the St. Charles and Lakefront airports in the Area C and Area D descriptions, respectively, and the Harvey VORTAC in the Area C description, but the airports and VORTAC information was omitted from the Class B description text header. This action makes the required edits above. Lastly, the descriptions have been edited to eliminate confusing wording and improve clarity.

The FAA is taking this action so that the current boundaries of the New Orleans Class B airspace area are not affected by the decommissioning of the ILS Runway 10 LOM.

# Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.9Y, airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014. FAA Order 7400.9Y is publicly available as listed in the **ADDRESSES** section of this final rule. FAA Order 7400.9Y lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points

#### The Rule

The FAA is amending Title 14 of the Code of Federal Regulations (14 CFR) part 71 by amending the New Orleans Class B airspace legal description for the Louis Armstrong New Orleans International Airport, New Orleans, LA. This action removes all references to the "ILS Runway 10 Outer Compass Locator" and replaces it in the Area A description with a point located at the same latitude/longitude geographic coordinates of the LOM. This rule updates the New Orleans International Airport-Moisant Field name to the Louis Armstrong New Orleans International Airport, and the ARP Geographic coordinates from "lat. 29°59'36" N., long. 90°15′28" W." to "lat. 29°59′36" N., long. 90°15′33″ W." Additionally, it updates the NAS New Orleans-Alvin Callender Field name to New Orleans Naval Air Station Joint Reserve Base (Alvin Callender Field), and the ARP geographic coordinates from "lat. 29°49′31″ N., long. 90°02′06″ W." to "lat. 29°49'38" N., long. 90°01'36" W." This action also adds the St. Charles and Lakefront Airports and their associated ARP geographic coordinates, as well as the Harvey VORTAC and its geographic coordinates to the legal description text header information. Lastly, the Class B airspace description is edited to remove confusing wording and improve clarity.

### **Regulatory Notices and Analyses**

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Since this action merely involves editorial changes in the legal description of the New Orleans Class B airspace area, and does not involve a change in the boundaries or altitudes or operating requirements of that airspace, notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

#### **Environmental Review**

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with 311a, FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures." This airspace action is an editorial change only and is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

## Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

# PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120, E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

### §71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014, is amended as follows:

Paragraph 3000 Subpart B—Class B Airspace.

# ASW LA B New Orleans, LA

Louis Armstrong New Orleans International
Airport (Primary Airport)
(Lat. 29°59′36″ N., long. 90°15′33″ W.)
New Orleans Naval Air Station Joint Reserve
Base (Alvin Callender Field), LA
(Lat. 29°49′38″ N., long. 90°01′36″ W.)
Ama, St. Charles Airport, LA (pvt)
(Lat. 29°57′07″ N., long. 90°17′10″ W.)
New Orleans, Lakefront Airport, LA
(Lat. 30°02′33″ N., long. 90°01′42″ W.)
Harvey VORTAC
(Lat. 29°51′01″ N., long. 90°00′11″ W.)

Area A. That airspace extending upward from the surface to and including 7,000 feet MSL within a 7-mile radius of the Louis Armstrong New Orleans International Airport and within a 1.5-mile radius of a point located at lat. 30°01′31″ N., long. 90°24′00″ W., excluding that airspace north of the south shore of Lake Pontchartrain, that airspace within and underlying Area C described hereinafter, and that airspace 0.5 mile either side of a line extending from lat. 30°01′10″

N., long. 90°07′47″ W. to lat. 29°59′31″ N., long. 90°15′37″ W. to lat. 30°03′37″ N., long. 90°22′10″ W.

Area B. That airspace extending upward from 600 feet MSL to and including 7,000 feet MSL north of the south shore of Lake Pontchartrain within a 7-mile radius of the Louis Armstrong New Orleans International Airport, excluding that airspace 0.5 mile either side of a line extending from lat. 30°01′10″ N., long. 90°07′47″ W. to lat. 29°59′31″ N., long. 90°15′37″ W. to lat. 30°03′37″ N., long. 90°22′10″ W.

Area C. That airspace extending upward from 1,000 feet MSL to and including 7,000 feet MSL within an area bounded by a line beginning 7 miles southwest of the Louis Armstrong New Orleans International Airport on the north shore of the Mississippi River; thence east along the Mississippi River north shore to a point 0.5 mile east of and parallel to the St. Charles Airport runway 17/35 extended centerline; thence southeast along a line 0.5 miles east of and parallel to the St. Charles Airport runway 17/35 extended centerline to the Southern Pacific Railroad track; thence southwest along the Southern Pacific Railroad track to a point 4 miles southwest of the Louis Armstrong New Orleans International Airport; thence counterclockwise along a 4-mile radius of the Louis Armstrong New Orleans International Airport to the north shore of the Mississippi River; thence east along the north shore of the Mississippi River to the Harvey VORTAC 300° radial; thence southeast along the Harvey VORTAC 300° radial to a point 7 miles southeast of the Louis Armstrong New Orleans International Airport; thence clockwise along the 7-mile radius of the Louis Armstrong New Orleans International Airport to the point of beginning.

Area D. That airspace extending upward from 2,000 feet MSL to and including 7,000 feet MSL within a 15-mile radius of the Louis Armstrong New Orleans International Airport, excluding that airspace within Areas A, B, and C previously described, that airspace within Area F described hereinafter, that airspace within the Lakefront Airport Class D airspace area, and that airspace within a 4.4-mile radius of New Orleans Naval Air Station Joint Reserve Base (Alvin Callender Field).

Area E. That airspace extending upward from 4,000 feet MSL to and including 7,000 feet MSL within a 20-mile radius of the Louis Armstrong New Orleans International Airport, excluding that airspace within Areas A, B, C, and D previously described, and that airspace within Area F described hereinafter.

Area F. That airspace extending upward from the surface to 1,000 feet MSL and from 2,000 feet MSL to 7,000 feet MSL 0.5 mile either side of a line extending from lat. 30°01′10″ N., long. 90°07′47″ W. to lat. 29°59′31″ N., long. 90°15′37″ W. to lat. 30°03′37″ N., long. 90°22′10″ W., excluding that airspace below 600 feet MSL north of the south shore of Lake Pontchartrain.

Issued in Washington, DC, on July 7, 2015. Gary A. Norek,

Manager, Airspace Policy and Regulations Group.

[FR Doc. 2015–17709 Filed 7–17–15; 8:45 am] BILLING CODE 4910–13–P

#### FEDERAL TRADE COMMISSION

16 CFR Parts 700, 701, and 703 RIN 3084-AB24; 3084-AB25; 3084-AB26

Final Action Concerning Review of Interpretations of Magnuson-Moss Warranty Act; Rule Governing Disclosure of Written Consumer Product Warranty Terms and Conditions; Rule Governing Pre-Sale Availability of Written Warranty Terms; Rule Governing Informal Dispute Settlement Procedures; and Guides for the Advertising of Warranties and Guarantees

**AGENCY:** Federal Trade Commission. **ACTION:** Final revised Interpretations; Final clerical changes to Rules; and Conclusion of review proceedings.

**SUMMARY:** The Federal Trade Commission ("the Commission") is announcing its final action in connection with the review of a set of warranty-related Rules and Guides: The Interpretations of the Magnuson-Moss Warranty Act ("Interpretations" or "part 700"); the Rule Governing Disclosure of Written Consumer Product Warranty Terms and Conditions ("Rule 701"); the Rule Governing Pre-Sale Availability of Written Warranty Terms ("Rule 702"); the Rule Governing Informal Dispute Settlement Procedures ("Rule 703"); and the Guides for the Advertising of Warranties and Guarantees ("the Guides" or "part 239"). The Interpretations represent the Commission's views on various aspects of the Magnuson-Moss Warranty Act ("the Act" or "MMWA"), and are intended to clarify the Act's requirements. Rule 701 specifies the information that must appear in a written warranty on a consumer product. Rule 702 details the obligations of sellers and warrantors to make warranty information available to consumers prior to purchase. Rule 703 specifies the minimum standards required for any informal dispute settlement mechanism that is incorporated into a written consumer product warranty, and that the consumer must use prior to pursuing any legal remedies in court. The Guides are intended to help advertisers avoid unfair or deceptive practices in the advertising of warranties or guarantees.

**DATES:** The changes to the Interpretations and Rules will take effect on July 20, 2015.

### FOR FURTHER INFORMATION CONTACT:

Svetlana S. Gans, Staff Attorney, Division of Marketing Practices, Federal Trade Commission, Washington, DC 20580, (202) 326–3708.

SUPPLEMENTARY INFORMATION: The MMWA, 15 U.S.C. 2301-2312, is the federal law that governs consumer product warranties. Passed by Congress in 1975, the Act requires manufacturers and sellers of consumer products to provide consumers with detailed information about warranty coverage before and after the sale of a warranted product. When consumers believe they are the victim of an MMWA violation, the statute provides them the ability to proceed through a warrantor's informal dispute resolution process or sue in court. On August 23, 2011, the Commission published a Federal Register request for public comment, soliciting written public comments concerning five warranty Rules and Guides: (1) The Commission's Interpretations of the Magnuson-Moss Warranty Act, 16 CFR part 700; (2) the Rule Governing Disclosure of Written Consumer Product Warranty Terms and Conditions, 16 CFR part 701; (3) the Rule Governing Pre-Sale Availability of Written Warranty Terms, 16 CFR part 702; (4) the Rule Governing Informal Dispute Settlement Procedures, 16 CFR part 703; and (5) the Guides for the Advertising of Warranties and Guarantees, 16 CFR part 239.1 The Commission requested comments on these Rules and Guides as part of its regulatory review program, under which it reviews rules and guides periodically in order to obtain information about the costs and benefits of the rules and guides under review, as well as their regulatory and economic impact. The information obtained assists the Commission in identifying rules and guides that warrant modification or rescission. After careful review of the comments received in response to the request, the Commission has determined to retain Rules 701, 702, and 703, and the Guides without change, and to modify the Interpretations in §§ 700.10 and 700.11(a). The Commission is also updating the citation format in the Interpretations and Rules.2

In addition, Commission staff has recently issued a number of guidance documents to better educate consumers and businesses concerning their rights and obligations under the MMWA. For example, in order to cure perceived misconceptions in the marketplace, staff issued and recently updated a consumer alert stating that the MMWA prohibits warrantors from voiding an automotive warranty merely because a consumer uses an aftermarket or recycled part or third-party services to repair one's vehicle (subject to certain exceptions).3 Staff also updated the .Com Disclosures to provide additional guidance concerning online warranty disclosure obligations 4 and issued letters to various online sellers concerning their obligations under the pre-sale availability rule.<sup>5</sup> Staff will continue to evaluate whether additional guidance is necessary to better inform both consumers and business concerning their rights and responsibilities under the MMWA.

# A. Background

1. 16 CFR Part 700: Interpretations of the Magnuson-Moss Warranty Act ("Interpretations")

The MMWA, 15 U.S.C. 2301–2312, which governs written warranties on consumer products, was signed into law on January 4, 1975. After the Act was passed, the Commission received many questions concerning the Act's requirements. In responding to these inquiries, the Commission initially published, on June 18, 1975, a policy statement in the **Federal Register** (40 FR 25721) providing interim guidance during the initial implementation of the Act. As the Commission continued to

receive questions and requests for advisory opinions, however, it determined that more comprehensive guidance was appropriate. Therefore, on July 13, 1977, the Commission published in the **Federal Register** (42 FR 36112) its Interpretations of the MMWA to assist warrantors and suppliers of consumer products in complying with the Act.

These Interpretations are intended to clarify the Act's requirements for manufacturers, importers, distributors, and retailers. The Interpretations cover a wide range of subjects, including: The types of products considered "consumer products" under the Act; the differences between a "written warranty," "service contract" and "insurance"; written warranty term requirements; the use of warranty registration cards under full and limited warranties; and illegal tying arrangements under Section 2302(c) of the Act. These Interpretations, like industry guides, are administrative interpretations of the law. Therefore, they do not have the force of law and are not independently enforceable. The Commission can take action under the Federal Trade Commission Act ("FTC Act") and the MMWA, however, against claims that are inconsistent with the Interpretations if the Commission has reason to believe that such claims are unfair or deceptive practices under Section 5 or violate the MMWA.

2. 16 CFR Part 701: Disclosure of Written Consumer Product Warranty Terms and Conditions

Section 2302(a) of the MMWA authorizes the Commission to promulgate rules regarding the disclosure of written warranty terms. Accordingly, on December 31, 1975, the Commission published in the Federal Register (40 FR 60188) its Rule Governing Disclosure of Written Consumer Product Warranty Terms and Conditions. Rule 701 establishes disclosure requirements for written warranties on consumer products that cost more than \$15.00. It also specifies the aspects of warranty coverage that must be disclosed in the written document, as well as the exact language that must be used for certain disclosures regarding state law on the duration of implied warranties and the availability of consequential or incidental damages.

Under Rule 701, warranty information must be disclosed in simple, easily understandable, and concise language in a single document. In promulgating Rule 701, the Commission determined that material facts about product warranties, the nondisclosure of which would be deceptive or misleading, must

<sup>&</sup>lt;sup>1</sup> 76 FR 52596 (Aug. 23, 2011).

<sup>&</sup>lt;sup>2</sup> These clerical changes do not involve any substantive changes in the Rules' requirements for entities subject to the Rules. Accordingly, the Commission finds that public comment is unnecessary. See 5 U.S.C. 553(b)(3)(B).

In addition, under the APA, a substantive final rule is required to take effect at least 30 days after

publication in the **Federal Register** unless an agency finds good cause that the rule should become effective sooner. 5 U.S.C. 553(d). However, this is purely a clerical change and is not a substantive rule change. Therefore, the Commission finds good cause to dispense with a delayed effective date.

<sup>&</sup>lt;sup>3</sup> FTC, Auto Warranties & Routine Maintenance (July 2011, updated May 2015) ("Consumer Alert on Auto Warranties"), available at http://www.consumer.ftc.gov/articles/0138-auto-warranties-routine-maintenance. A warrantor may condition the warranty on the use of certain parts or service if it provides these parts and services without charge to the consumer under the warranty, or alternatively, if the warrantor receives a waiver from the Commission. See 15 U.S.C. 2302(c).

<sup>&</sup>lt;sup>4</sup> See FTC, .com Disclosures: How to Make Effective Disclosures in Digital Advertising (2013), available at http://ftc.gov/os/2013/03/130312dotcomdisclosures.pdf.

<sup>&</sup>lt;sup>5</sup> Press Release, FTC, As Holiday Shopping Season Gets Underway, FTC Reminds Internet Retailers to Ensure Consumers Have Access to Warranty Information (Dec. 2, 2013), http:// www.ftc.gov/news-events/press-releases/2013/12/ holiday-shopping-season-gets-underway-ftcreminds-internet.

be disclosed.<sup>6</sup> In addition to specifying the information that must appear in a written warranty, Rule 701 also requires that, if the warrantor of a limited warranty uses a warranty registration or owner registration card, the warranty must disclose whether return of the registration card is a condition precedent to warranty coverage.<sup>7</sup>

# 3. 16 CFR Part 702: Pre-Sale Availability of Written Warranty Terms

Section 2302(b)(1)(A) of the MMWA directs the Commission to prescribe rules requiring that the terms of any written warranty on a consumer product be made available to the prospective purchaser prior to the sale of the product. Accordingly, on December 31, 1975, the Commission published Rule 702. Rule 702 establishes requirements for sellers and warrantors to make the text of any warranty on a consumer product available to the consumer prior to sale. Among other things, Rule 702 requires sellers to make warranties readily available either by: (1) Displaying the warranty document in close proximity to the product or (2) furnishing the warranty document on request and posting signs in prominent locations advising consumers that warranties are available. The Rule requires warrantors to provide materials to enable sellers to comply with the Rule's requirements, and also sets out the methods by which warranty information can be made available prior to the sale if the product is sold through catalogs, mail order, or door-to-door sales. As discussed further below, Rule 702 also applies to online sales.

## 4. 16 CFR Part 703: Informal Dispute Settlement Procedures

Section 2310(a)(2) of the MMWA directs the Commission to prescribe the minimum standards for any informal dispute settlement mechanism ("IDSM" or "Mechanism") that a warrantor, by including a "prior resort" clause in its written warranty, requires consumers to use before they may file suit under the Act to obtain a remedy for warranty non-performance. Accordingly, on December 31, 1975, the Commission published Rule 703. Rule 703 contains extensive procedural safeguards for consumers that a warrantor must incorporate in any IDSM. These

standards include, but are not limited to, requirements concerning the IDSM's structure (e.g., funding, staffing, and neutrality), the qualifications of staff or decision makers, and the IDSM's procedures for resolving disputes, recordkeeping, and annual audits.

# 5. 16 CFR Part 239: Guides for the Advertising of Warranties and Guarantees

The Guides for the Disclosure of Warranties and Guarantees, codified in part 239, provide guidance concerning warranty and guarantee disclosures. Part 239 intends to help advertisers avoid unfair and deceptive practices when advertising warranties and guarantees. The 1985 Guides advise that advertisements mentioning warranties or guarantees should contain a disclosure that the actual warranty document is available for consumers to read before they buy the advertised product. In addition, the Guides set forth advice for using the terms "satisfaction guarantee," "lifetime," and similar representations. Finally, the Guides advise that sellers or manufacturers should not advertise that a product is warranted or guaranteed unless they promptly and fully perform their warranty obligations. The Guides are advisory in nature.

# B. Analysis of the Comments on the Interpretations, Rule 701, Rule 702, Rule 703, and the Guides

Twenty-nine entities and individuals submitted public comments in response to the August 23, 2011 Federal Register request for public comment.8 Comments generally reflect a strong level of support for the view that the Interpretations, Rules, and Guides are achieving the objectives they were fashioned to achieve—i.e., to facilitate the consumer's ability to obtain clear, accurate warranty information. A majority of the commenters, though endorsing retention of the present regulatory scheme, suggested modifications to the Interpretations, Rules, and Guides, which they believe would provide greater consumer protections and minimize burdens on firms subject to the regulations.

- 1. 16 CFR Part 700: Interpretations
- a. Amend § 700.10 To Provide Further Guidance on Prohibited Tying

Generally, the MMWA prohibits warrantors from conditioning warranties on the consumer's use of a replacement product or repair service identified by brand or name, unless the article or service is provided without charge to the consumer or the warrantor has received a waiver.9 The Commission's Interpretations illustrate this concept by stating that phrases such as this warranty is void if service is performed by anyone other than an authorized "ABC" dealer and all replacement parts must be genuine "ABC" parts and the like, are prohibited unless the service or parts are provided free of charge. Such provisions violate the MMWA's ban on tying arrangements and are deceptive under Section 5 of the FTC Act, because a warrantor cannot avoid liability under a warranty where the defect or damage is unrelated to the consumer's use of "unauthorized" parts or service. This does not, however, preclude the warrantor from denying warranty coverage for repairs associated with defects or damage caused by the use of the "unauthorized" parts or service. <sup>10</sup> Several commenters <sup>11</sup> assert that the

Several commenters <sup>11</sup> assert that the Commission's Interpretations do not address the market realities of manufacturers' statements about the use of branded products. These commenters state that automotive and other consumer product manufacturers have employed language in consumer materials "to suggest that warranty coverage directly or impliedly 'requires' the use of a branded product or service" <sup>12</sup> leading reasonable consumers to believe that coverage under a written warranty will be void if

<sup>&</sup>lt;sup>6</sup> See 40 FR 60168, 60169 (Dec. 31, 1975) ("The items required for disclosure by this Rule are material facts about warranties, the non-disclosure of which constitutes a deceptive practice.").

<sup>&</sup>lt;sup>7</sup> Notably, section 2014(b)(1) of the MMWA prohibits warrantors offering a *full* warranty from imposing duties other than the notification of a defect as a condition of securing warranty remedies. 15 U.S.C. 2304(b)(1).

<sup>&</sup>lt;sup>8</sup>76 FR 52596 (Aug. 23, 2011). Public comments in response to the Commission's 2011 FRN are located at http://www.ftc.gov/policy/public-comments/initiative-392. Comments cited herein to the Federal Register notice are designated as such, and are identified by commenter name, and, where applicable, page number.

<sup>&</sup>lt;sup>9</sup> See 15 U.S.C. 2302(c). The Commission may waive this prohibition if the warrantor demonstrates to the Commission that the warranted product will function properly only if the article or service so identified is used in connection with the warranted product, and the waiver is in the public interest. 15 U.S.C. 2302(c).

<sup>&</sup>lt;sup>10</sup> 16 CFR 700.10.

<sup>&</sup>lt;sup>11</sup> Ashland: Automotive Oil Change Association: Automotive Recyclers Association; BP Lubricants; Certified Auto Parts Association: Hunton & Williams; International Imaging Technology Council; LKQ Corporation; Motor & Equipment Manufacturers Association: Monro Muffler Brake: Property Casualty Insurers Association of America; and the Uniform Standards in Automotive Products Coalition ("USAP Coalition"). One commenter, the American Insurance Association, urges the Commission not to change § 700.10. The Coalition for Auto Repair Equality urges the Commission to uphold MMWA's tying prohibitions. Grandpa's Garage comments that GM's recommendation that consumers use its branded oil is helpful because GM explains the right products to use for repair and the prevention of premature failure. Consumer J. McKee generally supports the tying prohibitions.

<sup>&</sup>lt;sup>12</sup> USAP Coalition at 6.

non-original parts or non-dealer services are utilized. 13 Commenters suggest that these statements lead consumers to doubt the viability of non-original (or recycled) parts.14""Faced with such a choice a consumer is likely to use the 'required' product in order to avoid the risk that they may later face potentially expensive repairs that may not be covered under their warranty, resulting in a 'tie' created *via* warranty." <sup>15</sup> Accordingly, these commenters request that the Commission "make clear that warranty language that creates the impression that the use of a branded product or service is required in order to maintain warranty coverage is . . . impermissible." 16

The MMWA incorporates principles under Section 5 of the FTC Act that prohibit warrantors from disseminating deceptive statements concerning warranty coverage. The MMWA gives the Commission the authority to restrain a warrantor from making a deceptive warranty, which is defined as a warranty that "fails to contain information which is necessary in light of all of the circumstances, to make the warranty not misleading to a reasonable individual exercising due care." 17 Thus, a warrantor would violate the MMWA if its warranty led a reasonable consumer exercising due care to believe that the warranty conditioned coverage "on the consumer's use of an article or service identified by brand, trade or corporate name unless that article or service is provided without charge to the consumer." 18

Moreover, misstatements leading a consumer to believe that the consumer's warranty is void because a consumer used "unauthorized" parts or service may also be deceptive under Section 5 of the FTC Act. 19 Specifically, claims by a warrantor that create a false impression that a warranty would be void due to the use of "unauthorized" parts or service may constitute a deceptive practice as outlined in the FTC Policy Statement on Deception: "The deception theory is based on the fact that most ads making objective claims imply, and many expressly state, that an advertiser has certain specific

grounds for the claims. If the advertiser does not, the consumer is acting under a false impression. The consumer might have perceived the advertising differently had he or she known the advertiser had no basis for the claim."  $^{20}$ A warrantor claiming or suggesting that a warranty is void simply because a consumer used "unauthorized" parts or service would have no basis for such a claim (absent a Commission waiver pursuant to Section 2302(c) of the Act). This is consistent with staff's view, as expressed in recent opinion letters, that misinformation and misleading statements in conjunction with warranty coverage may be actionable.21

Therefore, to clarify the tying prohibition of the MMWA, § 700.10(c) will be changed as described in amendatory instruction 11.

b. Require a Mandatory Disclosure Statement in Companies' Warranties

Several commenters 22 ask the Commission to mandate that warrantors providing a warranty to a consumer in connection with a motor vehicle incorporate standard language in their warranties, akin to the FTC's Consumer Alert on Auto Warranties.<sup>23</sup> These commenters state that, although the FTC's Consumer Alert on Auto Warranties informs consumers of their rights under the MMWA, consumers should receive information about these rights in an owner's manual or warranty document pursuant to a Commissionmandated disclosure. These commenters ask the Commission to amend its Interpretations so that these warrantors would be required to provide in boldface type on the first page of a written automobile warranty: "Warranty coverage cannot be denied unless the warrantor or service provide[r] [sic] can demonstrate that the defect or damage

was caused by the use of unauthorized articles or services." <sup>24</sup> Commenters base their recommendation, in part, on the language mandated by the Clean Air Act for use in user manuals, namely, that "maintenance, replacement, or repair of the emissions control devices and systems may be performed by any automotive repair establishment or individual using any automotive part." <sup>25</sup>

The Commission declines to make this change. As an initial matter, the MMWA, unlike the Clean Air Act, does not require a mandatory disclaimer on all warranties. Further, the current record lacks sufficient evidence to justify the imposition of a mandatory warranty disclosure requirement for a subset of warrantors.<sup>26</sup>

 c. Clarify That Use of an Aftermarket or Recycled Component is Not a Prima
 Facie Justification for Warranty Denial

One commenter 27 asks the Commission to clarify that the use of aftermarket components is not a prima facie justification for warranty denial. The Interpretations and related educational materials already make clear that the mere use of an aftermarket (or recycled) component alone is not a sufficient justification for warranty denial. As discussed above, a warrantor cannot disclaim warranty coverage if a defect or damage is unrelated to the consumer's use of "unauthorized" products or service, unless the warrantor provides the service or part without charge under the warranty or receives a Commission waiver.<sup>28</sup> Å warrantor can refuse coverage where the warrantor can demonstrate that the defect or damage was caused by the use of the "unauthorized" part or service.29

Several commenters ask the Commission to better educate consumers on how to identify and report warranty tying in the marketplace. In July 2011, the staff

 $<sup>^{\</sup>rm 13}\,\rm Hunton$  & Williams at 4.

 $<sup>^{14}\,\</sup>mathrm{Automotive}$  Recyclers Association at 2.

<sup>&</sup>lt;sup>15</sup> *Id*.

<sup>&</sup>lt;sup>16</sup> USAP Coalition at 3.

<sup>17 15</sup> U.S.C. 2310(c).

<sup>18 16</sup> CFR 700.10.

<sup>&</sup>lt;sup>19</sup> 15 U.S.C. 45(a). See generally Letter from James C. Miller III, Chairman, Fed. Trade Comm'n, et al., to Rep. John D. Dingell (Oct. 14, 1983), reprinted in Cliffdale Assocs., Inc., 103 F.T.C. 110, 174 (1984), available at https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception (hereinafter "FTC Policy Statement on Deception") at 2.

<sup>&</sup>lt;sup>20</sup> FTC Policy Statement on Deception, supra note 19 at n14; see also 15 U.S.C. 2310(c)(2).

 $<sup>^{21}\</sup>mathrm{Consumer}$  Alert on Auto Warranties, supra note 3.

<sup>&</sup>lt;sup>22</sup> Ashland at 3; Automotive Oil Change Association at 2; Certified Automotive Parts Association at 2–3; International Imaging Technology Council at 6–7; LKQ Corporation at 10; Monro Muffler Brake at 1–2; USAP Coalition at 14–15.

<sup>&</sup>lt;sup>23</sup> The Consumer Alert on Auto Warranties informs consumers, among other things, that unless they have been provided parts or services without charge under the warranty, they do not have to use the dealer for repairs and maintenance to keep their warranty in effect, stating, "An independent mechanic, a retail chain shop, or even you yourself can do routine maintenance and repairs on your vehicle. In fact, the Magnuson-Moss Warranty Act, which is enforced by the FTC, makes it illegal for manufacturers or dealers to claim that your warranty is void or to deny coverage under your warranty simply because someone other than the dealer did the work." Consumer Alert on Auto Warranties, supra note 3.

<sup>&</sup>lt;sup>24</sup> USAP Coalition at 14. Elsewhere, however, the commenters propose other specific language for the Commission to add to its Interpretations that would not be limited to mandatory disclosures in warranty documents but would extend to owner's manuals and other communications with prospective consumers. USAP Coalition at 20, Att. B; Automotive Oil Change Association at 6 (referring to "warranty documents and related communications.").

 $<sup>^{25}</sup>$  USAP Coalition at 14, citing 42 U.S.C. 7541(c)(3)(A).

<sup>&</sup>lt;sup>26</sup> The Specialty Equipment Market Association ("SEMA") asks the Commission to prepare a supplemental consumer alert to specifically reference "specialty parts." SEMA at 2. A supplemental consumer alert is not necessary as the existing consumer alert applies to all non-original (or recycled) parts.

<sup>&</sup>lt;sup>27</sup> Ashland at 2.

<sup>&</sup>lt;sup>28</sup> 16 CFR 700.10(c).

<sup>&</sup>lt;sup>29</sup> Id.

issued a consumer alert highlighting MMWA's tying prohibitions. The alert explained: "Simply using an aftermarket or recycled part does not void your warranty. The Magnuson-Moss Warranty Act makes it illegal for companies to void your warranty or deny coverage under the warranty simply because you used an aftermarket or recycled part." <sup>30</sup>

d. Require That Warrantors Have Substantiation for Their Performance Claims Regarding Non-Original Parts

Several commenters 31 ask the Commission to require that warrantors have substantiation for their claims that original equipment manufacturer ("OEM") parts work better than nonoriginal or recycled parts. This specific request is outside the purview of the Act and relates generally to the requirement under Section 5 of the FTC Act that companies have sufficient basis for their claims. Section 5 requires warrantors making performance claims regarding non-original or recycled parts to have a reasonable basis for those claims, thereby ensuring that such claims are not unfair, deceptive, false, or misleading. Similarly, advertisers must have adequate substantiation—or a reasonable basis—for any advertising claims they make before the claims are disseminated. Under the substantiation doctrine, "firms lacking a reasonable basis before an ad is disseminated violate Section 5 of the FTC Act." 32

# e. Require Warranty Denial To Be in Writing

The Commission's Interpretations state that a warrantor is not precluded from denying warranty coverage for defects or damage caused by the use of "unauthorized" parts or service if the warrantor "demonstrates" that the "unauthorized" parts or service caused a defect or damage to the vehicle.<sup>33</sup> Commenters <sup>34</sup> state that, in some instances, warrantors have denied warranty coverage without sufficiently demonstrating to consumers that the use of "unauthorized" parts or service

caused defects or damage to the consumer's vehicle by, for example, giving consumers a copy of a service bulletin or just "say[ing] so." <sup>35</sup> Commenters therefore ask the Commission to require, in its Interpretations, that warrantors provide consumers with a written statement to support any warranty denial claim.

The Commission does not believe a change is warranted because the current record lacks sufficient evidence showing that warrantors routinely deny warranty coverage orally without demonstrating to the consumer that the "unauthorized" part or service caused damage to the vehicle. At this time, the Commission believes the existing Interpretations adequately address this issue.

Simply providing a consumer with a copy of a service bulletin or denying coverage with a bald, unsupported statement that the "unauthorized" parts or service caused the vehicle damage would be insufficient under the Commission's existing Interpretations. Warrantors must have a basis for warranty denials by demonstrating to consumers that the use of "unauthorized" parts or service caused the defect or damage to the vehicle. Further, denying warranty coverage by simply pointing to a service bulletin that informs consumers that only "authorized" parts or service should be used to maintain warranty coverage may also violate the MMWA's proscriptions against tying.<sup>36</sup> Therefore, whether the demonstration is in writing or oral, a warrantor denying warranty coverage due to the use of "unauthorized" parts or service must show that such use caused the defect or damage to the vehicle.

f. The Scope of Auto Dealers' Responsibilities Under the MMWA and Interpretations

Two commenters <sup>37</sup> address the scope of auto dealers' (which fall under MMWA's definition of "supplier" <sup>38</sup>) responsibilities under the MMWA and Interpretations. <sup>39</sup> First, the National Consumer Law Center ("NCLC") asks the Commission to add an interpretation stating that a supplier enters into a service contract with a consumer whenever the supplier offers a service contract to the consumer, irrespective of whether the supplier is obligated to

perform under the service contract.<sup>40</sup> The Commission declines to add the requested interpretation.

Existing staff guidance provides that "sellers of consumer products that merely sell service contracts as agents of service contract companies and do not themselves extend written warranties' do not "enter into" service contracts.41 This guidance parallels the MMWA's provisions concerning a seller's liability under the MMWA for merely selling a third party's warranty: "only the warrantor actually making a written affirmation of fact, promise, or undertaking shall be deemed to have created a written warranty, and any rights arising thereunder may be enforced under this section only against such warrantor and no other person." 42

In keeping with the MMWA, the Commission's Interpretations concerning parties "actually making" a written warranty provide that a supplier who simply distributes or sells a consumer product warranted by another person or business is not liable for failure of the written warranty to comply with the Act. 43 Accordingly, the Commission will not add the requested interpretation concerning service contracts

The second commenter, the Center for Auto Safety, seeks clarity to address the discrepancy it perceives between the MMWA and the staff's guidance concerning the circumstances under which an auto dealer (i.e., supplier) can disclaim implied warranties when offering service contracts. It argues that, on one hand, Section 2308(a)(2) of the MMWA states: "no supplier may disclaim or modify . . . any implied warranty to a consumer with respect to such consumer product if . . . at the time of sale, or within 90 days thereafter, such supplier enters into a service contract with the consumer which applies to such consumer product. ''44 On the other hand, the FTC's Businessperson's Guide to Federal Warranty Law states: "[s]ellers of consumer products who make service contracts on their products are

<sup>&</sup>lt;sup>30</sup> See Consumer Alert on Auto Warranties, supra note 3. As stated in the updated consumer alert, the manufacturer or dealer can, however, require consumers to use select parts if those parts are provided to consumers free of charge under the warranty.

 $<sup>^{31}\,\</sup>mathrm{Ashland}$  at 6–7; LKQ Corporation at 8; USAP Coalition at 15–16.

<sup>&</sup>lt;sup>32</sup> FTC Policy Statement Regarding Advertising Substantiation, appended to Thompson Med. Co., 104 F.T.C. 648, 839 (1984), aff'd, 791 F.2d 189 (D.C. Gir. 1986).

<sup>&</sup>lt;sup>33</sup> 16 CFR 700.10(c).

<sup>&</sup>lt;sup>34</sup> Ashland at 3; Automotive Oil Change Association at 6–7; BP Lubricants at 3, Certified Auto Parts Association at 4–5; SEMA at 3; USAP Coalition at 15–16.

 $<sup>^{35}\!</sup>$  Certified Auto Parts Association at 5.

<sup>36 16</sup> CFR 700.10(c).

<sup>&</sup>lt;sup>37</sup> Center for Auto Safety at 2; NCLC at 10.

<sup>&</sup>lt;sup>38</sup>The MMWA defines "supplier" as "any person engaged in the business of making a consumer product directly or indirectly available to consumers." 15 U.S.C. 2301(4).

<sup>39</sup> Center for Auto Safety at 2.

<sup>&</sup>lt;sup>40</sup> NCLC at 10.

<sup>&</sup>lt;sup>41</sup> See FTC, The Businessperson's Guide to Federal Warranty Law, available at http:// www.business.ftc.gov/documents/bus01businesspersons-guide-federal-warranty-law; 15 U.S.C. 2308(a)(2).

<sup>42 15</sup> U.S.C. 2310(f).

<sup>&</sup>lt;sup>43</sup> 16 CFR 700.4. Section 700.4 further provides, however, that other actions and written and oral representations of such a supplier in connection with the offer or sale of a warranted product may obligate that supplier under the Act. If under State law the supplier is deemed to have "adopted" the written affirmation of fact, promise, or undertaking, the supplier is also obligated under the Act.

<sup>44 15</sup> U.S.C. 2308(a)(2).

prohibited under the Act from disclaiming or limiting implied warranties. . . . However, sellers of consumer products that merely sell service contracts as agents of service contract companies and do not themselves extend written warranties can disclaim implied warranties on the products they sell." <sup>45</sup>

The Commission does not believe any discrepancy exists. The confusion may stem from the usage of the word "supplier," defined in the MMWA as: "any person engaged in the business of making a consumer product directly or indirectly available to consumers." 46 Thus, "supplier" can mean either the entity that "enters into a service contract with the consumer" or the entity that "merely sells" a third-party's service contract, without more. The latter, as explained previously, 47 has not entered into a service contract with the consumer, and therefore Section 2308(a)(2) would not apply.48

Suppliers, however, are not immune from liability. If a supplier sells a service contract that obligates it to perform under the contract, it will be deemed to have entered into the service contract within the meaning of the statute. In addition, suppliers who extend service contracts utilizing misrepresentations or material omissions may be subject to liability under the MMWA and Section 5 of the FTC Act.<sup>49</sup>

# Enforce the Act

Commenters <sup>50</sup> encourage the Commission to enforce the MMWA. The Commission enforces the Act by monitoring consumer complaints, reviewing audit reports, advising warrantors of their obligations, educating consumers and businesses, and taking enforcement action where appropriate.<sup>51</sup>

g. Apply Rules to Leases And Define "Lease"

NCLC urges the Commission to amend § 700.10 to clarify that the MMWA covers consumer leases.<sup>52</sup> The majority of courts have found that a lessee meets the definition of "consumer" in the MMWA because warranty rights are transferred to lessees or the lessees are permitted to enforce the contract under state law, among other reasons.<sup>53</sup> As NCLC notes, however, some courts have held that a lessee does not meet the definition of "consumer." These courts have generally found that the definition of 'consumer'' presupposes a transaction that qualifies as a sale under the Act. and that the lease transaction at issue was not a qualifying sale.54 NCLC therefore asks the Commission to add a new Interpretation, as  $\S$  700.13, titled, "consumer leases," to provide explicitly that the Act applies to consumer leases.55

The Commission does not agree with the view held by a minority number of courts that lessees cannot be a "consumer" under the MMWA because each prong of the "consumer" definition 56 presupposes a sale to the end-consumer (which in this case is a lessee). Rather, as the majority of courts have held, lessees meet the definition of a "consumer" because warranty rights are either transferred to lessees or the lessees are permitted to enforce the contract under state law.<sup>57</sup> Given that a majority of courts hold that the MMWA applies to certain leases, consistent with past agency guidance,58 a new Interpretation is not necessary.

h. Certain 50/50 Warranties Should Be Interpreted To Violate the Act's Anti-Tying Prohibition

NCLC urges the Commission to reconsider its 2002 opinion letter <sup>59</sup> finding "50/50 warranties" permissible under the Act. Fifty/fifty warranties are those where the dealer promises to pay 50% of the labor costs and 50% of the parts cost, and the consumer pays the remainder. NCLC argues that allowing the warrantor to choose the repairs or parts is contrary to the goals of the MMWA, and leads to monopolistic pricing practices and a decrease in competition. <sup>60</sup>

Although the Commission found that 50/50 warranties may violate the Act in certain circumstances in its 1999 rule review, in 2002, the Commission clarified its position on 50/50 warranties. The Commission stated that the Act prohibits warrantors from conditioning their warranties on the use of branded parts or service where the warranted articles or services are "severable from the dealer's responsibilities under the warranty."61 Therefore, when a warranty covers only replacement parts, and the consumer pays the labor charges, the warrantor cannot mandate specific service or labor to install those parts. Conversely, when a warranty covers only labor charges, and the consumer pays for parts, the warrantor cannot mandate the use of specific parts. With 50/50 warranties, however, "the warranting dealer has a direct interest in providing the warranty service for which it is partly financially responsible. . . . Rather than conditioning the warranty on the purchase of a separate product or service not covered by the warranty, a 50/50 warranty shares the cost of a single product or service." 62 For that reason, the warrantor needs some control over the repair needed and quality of repair.<sup>63</sup> The Commission has decided to retain its 2002 position on 50/50 warranties. The Commission has reviewed the issue and believes that its 2002 interpretation continues to be correct.

<sup>&</sup>lt;sup>45</sup> The Businessperson's Guide to Federal Warranty Law, *supra* note 41.

<sup>&</sup>lt;sup>46</sup> 15 U.S.C. 2301(4).

<sup>&</sup>lt;sup>47</sup> The Businessperson's Guide to Federal Warranty Law, *supra* note 41.

<sup>&</sup>lt;sup>48</sup> 15 U.S.C. 2308(a)(2).

<sup>&</sup>lt;sup>49</sup> 15 U.S.C. 2306(b) (requiring warrantors and suppliers to clearly and conspicuously disclose service contract terms and conditions); 15 U.S.C. 45

<sup>&</sup>lt;sup>50</sup> LKQ Corp. at 1 and 5; Motor & Equipment Manufacturers Association at 2–3.

<sup>51</sup> See, e.g., Compl., BMW of N. Am., LLC, File No. 132 3150, available at https://www.ftc.gov/system/files/documents/cases/150319bmwcmpt.pdf (Fed. Trade Comm'n March 19, 2015); Consumer Alert on Auto Warranties, supra note 3. Consumers or businesses may file complaints with the Commission online through https://www.ftccomplaintassistant.gov or by calling the Commission's toll-free number, 1–877–FTC–HELP (1–877–382–4357).

<sup>52</sup> NCLC at 3.

<sup>&</sup>lt;sup>53</sup> See, e.g., Voelker v. Porsche Cars N. Am., Inc.,
353 F.3d 516 (7th Cir. 2003); Mago v. Mercedes-Benz, U.S.A., Inc., 142 P.3d 712 (Ariz. Ct. App. 2006); Am. Honda Motor Co. v. Cerasani, 955 So.2d 543 (Fla. 2007).

 <sup>&</sup>lt;sup>54</sup> See, e.g., Stark v. Maserati N. Am., Inc., 2010
 WL 4916981 (E.D.N.Y. Oct. 13, 2010); DiCintio v. DaimlerChrysler Corp., 768 NE.2d 1121 (N.Y. 2002).
 <sup>55</sup> NCLC at 5.

<sup>&</sup>lt;sup>56</sup> 15 U.S.C. 2301(3) ("The term 'consumer' means a buyer (other than for purposes of resale) of any consumer product, any person to whom such product is transferred during the duration of an implied or written warranty (or service contract) applicable to the product, and any other person who is entitled by the terms of such warranty (or service contract) or under applicable State law to enforce against the warrantor (or service contractor) the obligations of the warranty (or service contract).").

<sup>&</sup>lt;sup>57</sup> See, e.g., supra note 53.

<sup>&</sup>lt;sup>58</sup> The agency has provided similar guidance. See Advisory Opinion from Rachel Dawson to Raymond Asher (June 10, 1976) ("A leased product would be covered if the lease is essentially equivalent to a sale. For example, a product would be covered if the total compensation to be paid by the lessee is substantially equivalent to or in excess of the value of the product, and the lessee will own the product, or has an option to buy it for a nominal

consideration, upon full compliance with his obligations under the lease.").

<sup>59</sup> NCLC at 6–7, citing Letter from Donald S. Clark to Keith E. Whann (Dec. 2, 2002), available at http://www.ftc.gov/system/files/documents/ advisory\_opinions/national-independentautomobile-dealer-association/clark\_to\_whann\_ letter.pdf.

<sup>60</sup> NCLC at 6.

<sup>&</sup>lt;sup>61</sup> Letter from Donald S. Clark to Keith E. Whann (Dec. 2, 2002), *supra* note 59.

<sup>62</sup> Id. at 2.

<sup>&</sup>lt;sup>63</sup> *Id*.

i. The Commission's Interpretation Under § 700.11(a) Conflicts With the McCarran-Ferguson Act and Supreme Court Precedent

NCLC asserts that the Commission has incorrectly interpreted the meaning of the McCarran-Ferguson Act in § 700.11(a).<sup>64</sup> The McCarran-Ferguson Act provides that "[n]o Act of Congress shall be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance, or which imposes a fee or tax upon such business, unless such Act specifically relates to the business of insurance: Provided, That . . . the Sherman Act, . . . the Clayton Act, and . . . the Federal Trade Commission Act . . . shall be applicable to the business of insurance to the extent that such business is not regulated by State Law." 65 Section 700.11 states that agreements regulated by state law as insurance are subject to the MMWA "only to the extent they are not regulated in a particular state as the business of insurance." 66

NCLC states that the Interpretation is inconsistent with both the McCarran-Ferguson Act and Supreme Court precedent.67 First, NCLC argues that because the MMWA is not one of the three enumerated statutes (the Sherman Act, Clayton Act or the FTC Act), the correct standard is the standard applicable to all other federal statutes. In other words, the MMWA can regulate the business of insurance so long as it does not "invalidate, impair, or supersede" state law. Therefore, even if a state regulates a service agreement as the business of insurance, the MMWA may still apply.68 Second, NCLC asserts the Commission's Interpretation is contrary to Supreme Court precedent, Humana v. Forsyth, 525 U.S. 299 (1999). There, the Supreme Court held that states' regulation of insurance fraud would not displace remedies under federal law for the same misconduct because they do not "impair the insurance regulatory scheme." 69 Consequently, NCLC states, "even though state insurance law provides a remedial scheme for breach of a service contract regulated as insurance, the additional availability of Magnuson-Moss remedies for the same misconduct does not 'impair' the insurance regulatory scheme." 70

The Commission agrees that the McCarran-Ferguson Act's "invalidate, impair, or supersede" standard is applicable to the MMWA. The Commission will revise the Interpretation as described in amendatory instruction 12.

j. Amend Definition of "Consumer Product"

SEMA asks the Commission to amend the definition of "consumer product" to include specialty equipment.<sup>71</sup> The Commission has determined that no definitional change is warranted because specialty equipment is already covered by the definition of "consumer product." "Consumer product." is defined as "any tangible personal property which is distributed in commerce and which is normally used for personal, family, or household purposes." <sup>72</sup>

- 2. 16 CFR Part 701: Disclosure of Terms and Conditions (Rule 701)
- a. Regulate Service Contract Disclosures

The request for public comment specifically asked whether the Commission should amend the Rules to cover service-contract disclosures.<sup>73</sup>

The Commission received six comments on this issue: four commenters urge the Commission not to add specific servicecontract disclosure requirements, while two commenters take the opposite view.<sup>74</sup> The four opponents of disclosure rules for service contracts state that service contracts are different from warranties in that they do not form the basis of the bargain. They argue that no federal regulation is needed because states already regulate service contracts and adding federal regulation to the mix would create unnecessary burdens to both the industry and to federal and state governments.<sup>75</sup>

On the other hand, two commenters, Mr. Evan Johnson and NCLC, argue that the Commission should amend the Rules to prescribe the manner and form in which service-contract terms are disclosed. Mr. Johnson argues that service contracts have been a "huge source" of consumer complaints. "Many of these complaints concern marketing but many also arise from the unclear wording and structure of the contracts." <sup>76</sup> NCLC provides two reasons why the Commission should specifically regulate service contracts. First, the reasons for mandatory disclosure requirements for warranties apply equally to service contracts; regulating one and not the other makes little sense.<sup>77</sup> Second, service contracts

<sup>64</sup> NCLC at 9.

<sup>65 15</sup> U.S.C. 1012(b).

<sup>66 16</sup> CFR 700.11(a).

<sup>67</sup> NCLC at 8–9.

<sup>&</sup>lt;sup>68</sup> *Id.* at 8.

<sup>69</sup> Id. at 9.

<sup>&</sup>lt;sup>70</sup> Id.

<sup>&</sup>lt;sup>71</sup> SEMA at 2. Specialty equipment includes performance, functional, restoration and stylingenhancement products for use on passenger cars and light-duty trucks. *Id.* at 1.

<sup>72 16</sup> CFR 701.1(b).

<sup>73</sup> The Association of Home Appliance Manufacturers ("AHAM") asks for additional changes to Rule 701. First, AHAM asks the Commission to amend Rule 701.3 by adding that any warrantor complying with the Rule is entitled to a presumption in any breach of warranty litigation that the warranty is not unconscionable, deceptive, or misleading. AHAM at 2. It argues that consumers file hundreds of class actions each year asking courts to invalidate or modify the terms of a written warranty. Id. Although Rule 701.3 sets out minimum federal disclosure requirements for consumer product warranties, warrantors must also follow the proscriptions of Section 5 of the FTC Act, prohibiting unfair and deceptive practices, and various applicable state laws. Because there are other laws governing unfairness or deception in warranties, the Commission does not believe it would be appropriate to create a new provision in the Warranty Rules specifying that warrantors complying with Rule 701.3 are entitled to a presumption that their warranties are not unconscionable, deceptive, or misleading. Second, AHAM asks the Commission to amend Rule 701.3 by adding that a warrantor can exclude any latent defects that may manifest after the written warranty period expires. Id. at 3. AHAM asserts that many lawsuits seek to expand or modify the express warranty's terms after sale, and beyond the contractually-limited time period, to cover an alleged latent defect that manifests itself postwarranty period. However, Rule 701.3 focuses on disclosure requirements for consumer product warranties. It requires the disclosure of several items of material information in a clear and conspicuous manner. Rule 701.3 does not mandate specific warranty coverage. Nor does the Rule itself cover post-warranty conduct. Therefore, no change is warranted. Mr. Steinborn asks the Commission to modify Rule 701 so that third-party manufacturers

or re-fillers of consumables, such as ink and toner, must include a marking prominently displayed on the consumable that clearly directs the end user to contact the party that remanufactured the consumable (or its designee) for all warranty claims and information. Steinborn at 2. However, Rule 701 already requires that warranty terms include a stepby-step explanation of the procedure which the consumer should follow in order to obtain performance of any warranty obligation. 16 CFR 701.3(a)(5). For this reason, the Commission has chosen not to incorporate the specific change advocated by Mr. Steinborn.

<sup>&</sup>lt;sup>74</sup> Opponents of federal service-contract disclosure regulations are the AHAM, Florida Service Agreement Association, Service Contract Industry Council, and Property Casualty Insurers Association of America. Mr. Johnson and NCLC support the Commission's promulgation of servicecontract disclosure regulations.

<sup>&</sup>lt;sup>75</sup> See Florida Service Agreement Association at 2-3; Service Contract Industry Council at 2-3. For example, the Service Contract Industry Council states that thirty-five states specifically regulate service contracts on consumer goods, thirty-five states regulate service contracts on homes, and thirty-eight states regulate service contracts on motor vehicles. Commenters assert that many of these state laws provide greater protection to consumers than the MMWA by, for example, "ensuring that service contract obligors are financially sound and that their obligations to consumers are secure." Because the MMWA preempts state warranty law unless the state law affords protection to consumers greater than the requirement of Magnuson-Moss," these commenters argue that additional federal regulations may have little practical effect.

<sup>76</sup> Johnson at 4.

<sup>77</sup> NCLC at 12.

are widely sold and expensive, and consumers have little information concerning costs, coverage, and claims process.<sup>78</sup>

The Commission does not believe such a rule amendment is needed because the MMWA and Section 5 already require that warrantors, suppliers, and service contract providers clearly and conspicuously disclose service contract terms and conditions. Section 2306(b) of the Act provides: "[n]othing in this chapter shall be construed to prevent a supplier or warrantor from entering into a service contract with the consumer in addition to or in lieu of a written warranty if such contract fully, clearly, and conspicuously discloses its terms and conditions in simple and readily understood language." 79 In addition, Section 5 prohibits service contract providers from failing to clearly and conspicuously disclose material terms and conditions or otherwise deceiving consumers with respect to the scope and nature of service contracts. This is in accord with the Businessperson's Guidance to the MMWA: "If you offer a service contract, the Act requires you to list conspicuously all terms and conditions in simple and readily understood language." 80 The Commission has issued a number of consumer education pieces on service contracts and extended warranties and will take action where warranted.81

# 3. 16 CFR Part 702: Pre-Sale Availability Rule (Rule 702)

Generally, under Rule 702, sellers who offer written warranties on consumer products must include certain information in their warranties and make them available for review at the point of purchase. The Commission's request for public comment asked whether the Commission should amend Rule 702 to specifically address making warranty documents accessible online.

The Commission received seven comments on this specific question.<sup>82</sup>

One commenter noted at the outset that Rule 702 "continues to be very important to consumers. Consumers are very aware of warranties and use warranty differences as a basis for choosing a product. The current rule is a reasonable and cost-effective approach to providing the information." <sup>83</sup>

Three commenters ask the Commission to specifically reference Internet sales in Rule 702 and provide additional guidance on how retailers can comply with the Rule by referring consumers to warrantors' Web sites.84 Although Rule 702 does not explicitly mention online commerce, it applies to the sale of warranted consumer products online. Staff recently updated the .Com Disclosures to provide additional guidance on disclosure obligations in the online context. As stated in the updated .Com Disclosures, warranties communicated through visual text online are no different than paper versions and the same rules apply.85 Online sellers of consumer products can easily comply with the pre-sale availability rule in a number of ways. Online sellers can, for example, use "a clearly-labeled hyperlink, in close conjunction to the description of the warranted product, such as 'get warranty information here' to lead to the full text of the warranty." 86

As with other online disclosures, warranty information should be displayed clearly and conspicuously. Therefore, for example, warranty terms buried within voluminous "terms and conditions" do not satisfy the Rule's requirement that warranty terms be in close proximity to the warranted product. Further, general references to warranty coverage, such as "one year warranty applies," are also not sufficient.<sup>87</sup>

the Rule to permit private actions for violations of Rule 702. However, the MMWA already provides a private cause of action to any consumer "who is damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation" under the MMWA. 15 U.S.C. 2310(d)(1).

The Commission however, does not agree with the view endorsed by commenters 88 that offline sellers can comply with the pre-sale availability rule by advising buyers of the availability of warranties on the warrantor's Web site. The intent of the Rule is to make warranty information available at the point of sale. For brick and mortar transactions, the point of sale is in the store; for online transactions, the point of sale is where consumers purchase the product online.

The Commission agrees with the commenter who notes: "Internet availability, however, is not a substitute for availability as specified in Rule 702 because many consumers make little or no use of the internet, while those who do still need the information at the point of sale as a fallback for when they haven't obtained the information online or when they want to verify that their online information is accurate." <sup>89</sup>

In sum, because Rule 702 already covers the sale of consumer products online, and because staff has updated its .Com Guidance concerning compliance with pre-sale obligations online, the Commission has chosen not to engage in additional rulemaking as to Rule 702 at this time.

## 4. Rule 703—Informal Dispute Settlement Procedures

The Commission's request for public comment specifically asked whether it should change Rule 703, and if so, how. Six commenters submitted responses to this question.90 At the outset, commenters highlighted the importance of the Rule in serving as a standard for IDSMs in general, and more specifically, in providing a benchmark for state lemon law IDSMs and certification programs for IDSMs. Many states' criteria focus on the IDSM's compliance with Rule 703's provisions. Therefore, commenters stressed that any repeal or change to Rule 703 will also affect state lemon law and certification programs. 91 Notwithstanding this fact, some commenters ask the Commission to change certain elements of the Rule,

<sup>&</sup>lt;sup>78</sup> Id.

<sup>79 15</sup> U.S.C. 2306(b).

<sup>&</sup>lt;sup>80</sup> The Businessperson's Guide to Federal Warranty Law, *supra* note 41.

<sup>&</sup>lt;sup>81</sup> See, e.g., FTC, Auto Service Contracts and Warranties, http://www.consumer.ftc.gov/articles/0054-auto-service-contracts-and-warranties; see also FTC v. Voicetouch, Civ. No. 09CV2929 (N.D. Ill., filed May 13, 2009) (action involving deceptive telemarketing of extended auto warranties); FTC v. Transcontinental Warranty, Inc., Civ. No. 09CV2927 (N.D. Ill., filed May 13, 2009) (same). The Commission will continue to examine service contract disclosures.

<sup>82</sup> AHAM at 3; Center for Auto Safety at 2; Eisenberg at 1; Johnson at 2–3; National Automobile Dealers Association at 2; National Independent Automobile Dealers Association at 2; Steinborn at 2–3. Ms. Eisenberg asks the Commission to amend

<sup>83</sup> Johnson at 2

<sup>&</sup>lt;sup>84</sup> AHAM at 3; National Independent Automobile Dealers Association at 2; Steinborn at 2–3. The Center for Auto Safety recommends that Rule 702.3 point of sale requirements be maintained and enforced, requiring hard copy warranty materials to be available at physical retail locations, not on CD or DVD. Staff's guidance allows warranties to be available on CDs and DVDs, but does not allow sellers to meet their pre-sale obligations by referring consumers to CDs or DVDs that are not readily accessible at the point of sale. See Letter from Allyson Himelfarb to Thomas M. Hughes (Feb. 17, 2009), available at http://www.ftc.gov/bcp/warranties/opinion0901.pdf.

 $<sup>^{85}</sup>$  See .com Disclosures, supra note 4, at 3, n7.

<sup>&</sup>lt;sup>87</sup> FTC Staff has found several instances in which online sellers have not fully complied with the presale availability rule and has contacted these sellers

to inform them of their obligations. http://www.ftc.gov/opa/2013/12/warningletters.shtm

<sup>&</sup>lt;sup>88</sup> AHAM at 4–5; see also Steinborn at 2 ("Where manufacturers and resellers have Internet presences, click-through access to and/or a conspicuous reference to the manufacturers' Web site containing the applicable warranty should be recognized as sufficient means for sellers to meet the requirements of 702.").

 $<sup>^{89}\,</sup> Johnson$  at 2.

<sup>&</sup>lt;sup>90</sup> AHAM at 6; Center for Auto Safety at 1; Johnson at 3; International Association of Lemon Law Administrators at 1; NCLC at 14–15; Nowicki at 1–2.

<sup>&</sup>lt;sup>91</sup> See International Association of Lemon Law Administrators at 1.

including the Mechanism's procedure, record-keeping, and audit requirements, and also reassess the Commission's position on binding arbitration clauses in warranty contracts. These comments are discussed below. Overall, the Commission leaves Rule 703 unchanged.

# a. Modify the IDSM Procedures

AHAM claims that the procedures prescribed in Rule 703 are difficult to follow and implement.92 It urges the Commission to simplify the procedures so they would be "more easily and widely implemented by warrantors." 93 It further asserts that "a change would benefit consumers, businesses, and courts by streamlining the dispute resolution procedure and, thereby, reducing the burden on state and federal courts of adjudicating some warranty disputes, as many more could be handled through informal, but structured proceedings." 94 AHAM does not proffer any specific changes that should be made, or provide examples of why the procedures described in Rule 703 are difficult to follow. As the Commission stated in 1975 when adopting the Rule, "[t]he intent is to avoid creating artificial or unnecessary procedural burdens so long as the basic goals of speed, fairness, and independent participation are met." 95 Further, staff's review of IDSM audits have not indicated any significant concern with IDSM procedures. The Commission therefore retains the Rule 703 procedures.

# b. Change Rules on Mechanism and Auditor Impartiality

Two commenters 96 state that Rule 703.4 should be amended because neither the Mechanism nor the auditor, who is selected by the Mechanism, is impartial. Mr. Nowicki asks the Commission to require the Mechanism to be completely independent of any warrantor or trade association. Further, both the Center for Auto Safety and Mr. Nowicki assert that a Mechanism should not select an auditor because doing so creates a conflict of interest. The Center for Auto Safety recommends that the Commission select an auditor for a fee, and determine whether the Mechanisms are fair and expeditious.

No changes are warranted because Rule 703 already imposes specific requirements concerning the impartiality of both the Mechanism and

the auditor that the Mechanism selects. For example, Rule 703.3(b) requires the warrantors and sponsors of IDSMs to take all necessary steps to ensure that the Mechanism, and its members and staff, are sufficiently insulated from the warrantor and the sponsor, so that the members' and staff's decisions and performance are not influenced by either the warrantor or the sponsor.97 The Rule imposes minimum criteria in this regard: (1) Committing funds in advance; (2) basing personnel decisions solely on merit; and (3) not assigning conflicting warrantor or sponsor duties to the Mechanism.98 Additional safeguards for impartiality are set forth in Rule 703.4 governing qualification of members.

As to auditors' impartiality, although the Mechanism may select its own auditor, Rule 703.7(d) provides that "[n]o auditor may be involved with the Mechanism as a warrantor, sponsor or member, or employee or agent thereof, other than for purposes of the audit." <sup>99</sup> Further, IDSM audits have found "no situation of conflict or circumstance which might give rise to an impression that [a conflict of interest] exists." <sup>100</sup> Therefore, the Rule contains sufficient safeguards against partiality.

# c. Modify the Information To Be Submitted to the Mechanism

Rule 703.5(d) requires the Mechanism to render a decision "at least within 40 days of notification of the dispute." 101 The Center for Auto Safety asks the Commission to amend Section 703.5 to provide that the "40 day deadline begins upon the consumer filing a substantially complete application regardless of whether the VIN is provided or not." 102 The Center for Auto Safety claims that the Better Business Bureau is evading the 40-day deadline, because the BBB does not request Vehicle Identification Number ("VIN") information on its consumer intake form but the BBB will only begin to consider the dispute after it receives the VIN number.

Section 703.5 requires the Mechanism to "investigate, gather and organize all information necessary for a fair and expeditious decision in each

dispute." 103 This provision "implicitly permits Mechanisms to require consumers to provide the Mechanism with information 'reasonably necessary' to decide the dispute." 104 When adopting the final Rule in 1975, the Commission noted the Rule's "intent is to avoid creating artificial or unnecessary procedural burdens so long as the basic goals of speed, fairness and independent participation are met." 105 Therefore, because the Mechanism must have some flexibility in deciding the information necessary for it to make a determination, the Commission will retain Rule 703.5 unchanged. The Commission encourages, however, open dialogue between industry groups and the BBB to address any remaining concerns. $^{106}$ 

# d. Mechanism's Decisions as Non-Binding

The Commission received three comments concerning Rule 703.5(j)'s provision prohibiting binding arbitration provisions in warranty contracts. <sup>107</sup> AHAM urges the Commission to delete this provision because "it creates disincentives for manufacturers or sellers to create a Mechanism in the first instance and leads to wasted and duplicative efforts in cases between the consumers and manufacturers or sellers." <sup>108</sup> NCLC and Mr. Johnson ask the Commission to retain Rule 703.5(j). <sup>109</sup>

When the Commission first promulgated Rule 703.5(j) in 1975, it did so based on the MMWA's language, legislative history, and purpose: to ensure that consumer protections were in place in warranty disputes. 110 The Commission explained that "reference within the written warranty to any binding, non-judicial remedy is prohibited by the Rule and the Act." 111 The Commission's underlying premise was that its authority over Mechanisms encompassed all nonjudicial dispute resolution procedures referenced within a written warranty, including arbitration.

During the 1996–97 rule review, some commenters asked the Commission to deviate from its position that Rule 703

<sup>92</sup> AHAM at 6.

<sup>&</sup>lt;sup>93</sup> Id.

<sup>94</sup> Id.

<sup>95 40</sup> FR 60168, 60193 (Dec. 31, 1975).

<sup>96</sup> Center for Auto Safety at 1; Nowicki at 1.

<sup>97 16</sup> CFR 703.3(b).

<sup>&</sup>lt;sup>98</sup> Id.

<sup>99 16</sup> CFR 703.7(d).

<sup>100</sup> See, e.g., Morrison and Company, 2013 Audit of BBB Auto Line, available at http://www.ftc.gov/sites/default/files/documents/reports\_annual/2013-audit-better-business-bureau-auto-line-including-state-florida-and-state-ohio/2013bbbautoline.pdf, at 6. The audit further found that "consumers are pleased with the impartiality and the quality of dispute resolution services . . . ." Id.

<sup>&</sup>lt;sup>101</sup> 16 CFR 703.5(d).

<sup>102</sup> Center for Auto Safety at 1.

<sup>&</sup>lt;sup>103</sup> 16 CFR 703.5(c).

<sup>&</sup>lt;sup>104</sup> See Staff Advisory Opinion to Mr. Dean Determan, at 6, n6 (Aug. 28, 1985).

<sup>&</sup>lt;sup>105</sup> 40 FR 60168, 60193 (Dec. 31, 1975).

<sup>&</sup>lt;sup>106</sup> According to the BBB Autoline program, a claim is initiated only after a consumer provides the VIN and signs the application. A claim cannot be initiated online without this information.

 $<sup>^{107}\,</sup>See$  NCLC at 13–14; Johnson at 3; AHAM at 6.

<sup>108</sup> AHAM at 6-7.

 $<sup>^{109}</sup>$  NCLC at 13–18; Johnson at 3.

<sup>&</sup>lt;sup>110</sup> 40 FR 60168, 60210 (Dec. 31, 1975).

<sup>111 40</sup> FR 60168, 60211 (Dec. 31, 1975).

bans mandatory binding arbitration in warranties. The Commission, however, relying on its previous analysis and the MMWA's statutory language, reaffirmed its view that the MMWA and Rule 703 prohibit mandatory binding arbitration. 112 As the Commission noted, Section 2310(a)(3) of the MMWA states that, if a warrantor incorporates an IDSM provision in its warranty, "the consumer may not commence a civil action (other than a class action). . . unless he initially resorts to such procedure." 113 The Commission concluded "Rule 703 will continue to prohibit warrantors from including binding arbitration clauses in their contracts with consumers that would require consumers to submit warranty disputes to binding arbitration." 114

Since the issuance of the 1999 FRN, courts have reached different conclusions as to whether the MMWA gives the Commission authority to ban mandatory binding arbitration in warranties.115 In particular, two appellate courts have questioned whether Congress intended binding arbitration to be considered a type of IDSM, which would potentially place binding arbitration outside the scope of the MMWA.<sup>116</sup> Nonetheless, the Commission reaffirms its long-held view that the MMWA disfavors, and authorizes the Commission to prohibit, mandatory binding arbitration in warranties. 117

First, as the Commission observed during the 1999 rule review, the text of section 2310(a)(3)(C)(i) contemplates that consumers will "initially resort" to IDSMs before commencing a civil action. That language clearly presupposes that "a mechanism's decision cannot be binding, because if it were, it would bar later court action." <sup>118</sup> Similarly, section 2310(a)(3)(C) specifies that "decisions" in IDSMs shall be admissible in any subsequent "civil action." <sup>119</sup> As that language confirms, Congress intended

that IDSMs resulting in a "decision"— *i.e.*, arbitration decisions rather than conciliation or mediation mechanisms—would precede and influence, but not foreclose, a subsequent judicial decision.

As the Commission has previously noted, the legislative history provides additional evidence that Congress intended all IDSMs, including arbitration proceedings, to be nonbinding. 120 The House committee report stated that "[a]n adverse decision in any informal dispute settlement proceeding would not be a bar to a civil action on the warranty involved in the proceeding. . . ." 121 That language confirms what Congress strongly implies in the statutory text: arbitration should precede but not preclude a subsequent court action.

The statutory scheme forecloses any argument that warranty-related arbitration proceedings fall outside the statutory category of "informal dispute resolution mechanisms" and thus outside the FTC's rulemaking authority. As many legislators, policymakers, and courts understood at the time of the MMWA's enactment, any arbitration proceeding is, by comparison to judicial proceedings, an "informal" "mechanism" for "dispute settlement," and it thus falls squarely within the plain meaning of the term "informal dispute settlement mechanism." 122 Similarly, the MMWA's conference report indicates that "arbiters"—i.e., the decisionmakers in any arbitration proceeding—are responsible for making determinations in IDSMs, and thus further confirms that arbitration is a form of IDSM.123

Just as important, any argument that an "arbitration" can somehow elude classification as an IDSM would subvert the purposes of the MMWA's IDSM provisions. To effectuate its declared policy of encouraging IDSMs that "fairly and expeditiously" settle consumer disputes, Congress: (1) Created incentives for warrantors to develop IDSMs and (2) directed the Commission to issue and enforce baseline rules for IDSMs.<sup>124</sup> Congress would not have created this elaborate structure for warrantor incentives and agency supervision of warrantors who want to mandate use of certain contractual procedures in their warranties, while simultaneously permitting warrantors to evade that structure simply by using another contractual procedure and calling it something else (e.g., "binding arbitration") and thereby immunizing it from all agency oversight.125 Other courts have upheld binding arbitration in this context on the ground that the rationale of Rule 703 demonstrates an impermissible hostility toward arbitration in general and binding arbitration in particular. 126 The Commission does not believe this is correct. Like the statutory text, the Commission's rules encourage arbitration proceedings when they comply with IDSM procedural safeguards and are not both mandatory and binding. Moreover, the Commission's rules permit "postdispute" binding arbitration, where the parties agree—after a warranty dispute has arisen—to resolve their disagreement through arbitration.127 The Commission has also recognized that post-Mechanism binding arbitration is allowed. 128 The Commission's prohibition is limited only to instances where binding arbitration is incorporated into the terms of a written warranty governed by the MMWA. 129

AHAM also argues that eliminating the prohibition on binding arbitration would remove disincentives for warrantors to create a Mechanism and reduce judicial costs spent dealing with duplicative warranty cases. However,

 $<sup>^{112}\,64</sup>$  FR 19700, 19708 (Apr. 22, 1999).

<sup>&</sup>lt;sup>113</sup> *Id.* (quoting 15 U.S.C. 2310(a)(3)(C)(i)).

<sup>&</sup>lt;sup>114</sup> 64 FR 19700, 19708 (Apr. 22, 1999).

<sup>115</sup> See, e.g., Kolev v. Euromotors West/The Auto Gallery, 658 F.3d 1024 (9th Cir. 2011), withdrawn, 676 F.3d 867 (9th Cir. 2012) (withdrawn pending the issuance of a decision on a separate issue by the California Supreme Court in Sanchez v. Valencia Holding Co., \$199119); Davis v. Southern Energy Homes, Inc., 305 F.3d 1268 (11th Cir. 2002); Walton v. Rose Mobile Homes, LLC, 298 F.3d 470 (5th Cir. 2002); see also Seney v. Rent-A-Center, Inc., 738 F.3d 631 (4th Cir. 2013).

 <sup>&</sup>lt;sup>116</sup> Davis v. Southern Energy Homes, Inc., 305
 F.3d 1268 (11th Cir. 2002); Walton v. Rose Mobile Homes, LLC, 298 F.3d 470 (5th Cir. 2002).

 $<sup>^{117}\,</sup>See~40$  FR 60168, 60210 (Dec. 31, 1975) and 64 FR 19700, 19708 (Apr. 22, 1999).

<sup>118 64</sup> FR 19700, 19708 (Apr. 22, 1999).

<sup>&</sup>lt;sup>119</sup> 15 U.S.C. 2310(a)(3).

<sup>&</sup>lt;sup>120</sup> 64 FR 19700, 19708 (Apr. 22, 1999).

<sup>&</sup>lt;sup>121</sup>Report to Accompany H.R. 7917, H.R. Rep. No. 93–1107, at 41 (1974) (report of the House Committee on Interstate and Foreign Commerce); see also S. Rep. No. 93–151, at 3 (1973) (report of the Senate Committee on Commerce) ("[I]f the consumer is not satisfied with the results obtained in any informal dispute settlement proceeding, the consumer can pursue his legal remedies in a court of competent jurisdiction. . . .").

<sup>122</sup> See, e.g., 119 Cong. Rec. 33,498 (1973) (statement of Sen. Magnuson); Consumer Protection: Hearings Before the Consumer Subcomm. of the S. Comm. on Commerce, S. Doc. No. 91–48, at 69 (1969) (statement of FTC Commissioner Elman); Alexander v. Gardner-Denver Co., 415 U.S. 36, 58 (1974). The Supreme Court has repeatedly confirmed that arbitration is a method of informal dispute resolution. See, e.g., AT&T Mobility LLC v. Concepcion, 131 S. Ct. 1740, 1749 (2011) ("[T]he informality of arbitral proceedings is itself desirable, reducing the cost and increasing the speed of dispute resolution."); Mitsubishi Motors v. Soler Chrysler-Plymouth, Inc., 473 U.S. 614, 628 (1985) ("By agreeing to arbitrate . ., [a party] trades the procedures and opportunity for review of the courtroom for the simplicity, informality, and expedition of arbitration.").

<sup>&</sup>lt;sup>123</sup> Section 2304(b)(1) prohibits warrantors from imposing any additional duty on consumers unless

the duty has been found reasonable in "an administrative or judicial enforcement proceeding" or "an informal dispute settlement proceeding." 15 U.S.C. 2304(b)(1). The conference report indicates that the reasonableness of the additional duty is to be determined by "the Commission, an arbiter, or a court." S. Rep. No. 93–1408, at 25, H.R. Rep. No. 93–1606, at 25 (1974) (Conf. Rep.) (emphasis added).

<sup>124 15</sup> U.S.C. 2310(a)(1)-(4).

<sup>&</sup>lt;sup>125</sup> 9 U.S.C. 1–16.

 $<sup>^{126}</sup>$  See, e.g., Davis v. S. Energy Homes, Inc., 305 F.3d 1268 (11th Cir. 2002).

<sup>127</sup> See 40 FR 60168, 60211 (Dec. 31, 1975).

<sup>128</sup> Id

<sup>129</sup> Id.

Congress already considered the issues of warrantor incentives and availability of judicial remedies. To encourage warrantors to create Mechanisms, Section 2310(a)(3) allows warrantors to specify that use of a Mechanism is a prerequisite to filing a MMWA suit. <sup>130</sup> The Commission believes that the current Rule appropriately implements the incentive structure that Congress established in the MMWA.

## e. Change the Statistical Requirements

Rule 703.6 requires the Mechanism to prepare indices and statistical compilations on a variety of issues, including warrantor performance, brands at issue, all disputes delayed beyond 40 days, and the number and percentage of disputes that were resolved, decided, or pending. 131 The Commission requires the compilation of indices and statistics in part so any person can review a Mechanism's files. "On the basis of the statistically reported performance, an interested person could determine to file a complaint with the Federal Trade Commission . . . and thereby cause the Commission to review the bona fide operation of the dispute resolution mechanism." 132

Two commenters, the Center for Auto Safety and Mr. Nowicki, ask the Commission to repeal the Mechanism's record-keeping requirements contained in Rule 703.6.<sup>133</sup> The Center for Auto Safety claims that most of the categories for statistical analysis "are ambiguous, misleading or deceptive. Unfavorable consumer outcomes can be reported as favorable; untimely resolutions can be reported as timely." <sup>134</sup>

Similar comments were received during the previous rule review. Then, commenters urged the Commission to abolish Rule 703.6 because the categories of statistical compilation were "either moot, nebulous, or even worse, misleading or deceptive." 135 The Commission then stated that it appreciated that Rule 703.6(e)'s statistical compilations cannot provide an in-depth picture of the workings of the Mechanism. "However, the statistics were not intended to serve that function. The statistical compilations attempt to provide a basis for minimal review by the interested parties to

determine whether the IDSM program is working fairly and expeditiously. Based on that review, a more detailed investigation could then be prompted." 136 In addition, the Commission was mindful of the costs associated with substantial recordkeeping requirements, so as not to discourage the establishment of IDSMs. "Therefore, the Commission sought to minimize the costs of the recordkeeping burden on the IDSM while ensuring that sufficient information was available to the public to provide a minimal review." 137 The Commission has reviewed the issue and believes that its previous position continues to be correct.

# f. Audits and Recordkeeping Availability

Rule 703.7 contains the audit requirements for the Mechanism. The Rule requires that an audit be performed annually evaluating: (1) Warrantors' efforts to make consumers aware of the Mechanism and (2) a random sample of disputes to determine the adequacy of the Mechanism's complaint intakeprocess and investigation and accuracy of the Mechanism's statistical compilations. 138 Each audit should be submitted to the Commission and made available to the public at a reasonable cost. For the last several years, the Commission has published the audits on its Web site, making them available to the public free of charge.

One commenter asks the Commission to change Rule 703.8 to "mak[e] all IDSM documents available online, and requir[e] the Commission to review samples of disputes to determine whether the mechanism fairly and expeditiously resolves disputes." 139 Another commenter recommends that the Commission repeal the audit requirements for the same reasons as the statistical compilation requirements. 140 Similar to the Commission's reasoning in upholding the statistical compilation requirements, the Commission has decided to retain the audit requirements without change for two reasons. First, like the statistical compilation requirements, the audit function attempts to provide a general basis for interested parties to determine whether the IDSM program is working fairly and expeditiously. Second, the IDSM must make available the statistical summaries to interested parties upon request, and hold open meetings to hear and decide

disputes. 141 Given that Rule 703 already contemplates public access to Mechanism information, and that the Commission was mindful that substantial recordkeeping costs may discourage the establishment of IDSMs, the Commission will not impose at this time a mandatory electronic access requirement. Further, the Commission staff reviews the audits annually and confirms they are Rule 703 compliant. For these reasons, the Commission retains Rule 703.8 unchanged.

# 5. 16 CFR Part 239: Warranty Guides

Several commenters ask the Commission to revise its Warranty Guides. First, three commenters 142 ask the Commission to modify § 239.2 to allow for the advertising of warranties online. The Commission's Guides are not specific to any medium, and already are applicable to all media. Second, commenters recommend that the Guides provide explicit, detailed guidance explaining how retailers and warrantors can comply with the MMWA. As stated previously, the .Com Disclosures and the Businessperson's Guide to Federal Warranty Law both provide additional guidance concerning online disclosure obligations. Therefore, part 239 will remain unchanged. 143

# **List of Subjects**

16 CFR Part 700

Trade practices, Warranties.

16 CFR Part 701

Trade practices, Warranties.

16 CFR Part 703

Trade practices, Warranties.

For the reasons set forth above, the Federal Trade Commission amends 16 CFR parts 700, 701, and 703 as follows:

<sup>&</sup>lt;sup>130</sup> 15 U.S.C. 2310(a)(3).

<sup>&</sup>lt;sup>131</sup> See generally 16 CFR 703.6(b)-(e).

<sup>132 40</sup> FR 60168, 60213 (Dec. 31, 1975).

 $<sup>^{133}</sup>$  Center for Auto Safety at 1; Nowicki at 2.

<sup>&</sup>lt;sup>134</sup>Center for Auto Safety at 1. Nowicki claims that empirical evidence suggests that the "compliance self-proclamations" may be false and warranties may be deceptive.

 $<sup>^{135}</sup>$  See 64 FR 19700, 19710 (Apr. 22, 1999) (discussing Mr. Nowicki's comment).

<sup>136</sup> Id.

<sup>137</sup> Id.

<sup>138 16</sup> CFR 703.7.

<sup>139</sup> Nowicki at 2.

<sup>&</sup>lt;sup>140</sup>Center for Auto Safety at 1.

<sup>141 16</sup> CFR 703.8.

<sup>&</sup>lt;sup>142</sup> AHAM at 3; National Automobile Dealers Association at 2; Steinborn at 3.

<sup>143</sup> AHAM and Steinborn ask the Commission to amend part 239 to recognize that "referral of consumers to manufacturer Internet sites which make available warranty information satisfies the requirement to disclose the actual product warranty information prior to purchase by consumer. AHAM at 3; Steinborn at 3-4. Such reference is already contemplated for online retailers. Such reference, however, would be contrary to the requirements imposed for offline retailers, as discussed above. Second, AHAM recommends that the Guides be amended to require advertisers ' clearly and conspicuously disclose what component/system is warranted and for what duration and if the balance of the product is not covered or covered for a different duration disclose that as well to prevent the consumer from believing that the terms of the warranty apply to the entire product." AHAM at 3-4. These requirements, however, are already encompassed in Rule 701.3(a)(2) and therefore not needed in the Guides.

# PART 700—INTERPRETATIONS OF MAGNUSON-MOSS WARRANTY ACT

■ 1. The authority citation for part 700 continues to read as follows:

Authority: Magnuson-Moss Warranty Act, Pub. L. 93–637, 15 U.S.C. 2301.

■ 2. Amend § 700.1 by revising the second and fifth sentences of paragraph (g) and the first sentence of paragraph (i) to read as follows:

#### § 700.1 Products covered.

\* \* \* \* \* \*

- (g) \* \* \* Section 103, 15 U.S.C. 2303, applies to consumer products actually costing the consumer more than \$10, excluding tax.\* \* \* This interpretation applies in the same manner to the minimum dollar limits in section 102, 15 U.S.C. 2302, and rules promulgated under that section.
- (i) The Act covers written warranties on consumer products "distributed in commerce" as that term is defined in section 101(13), 15 U.S.C. 2301(13).
- 3. Amend § 700.2 by revising the first sentence to read as follows:

### § 700.2 Date of manufacture.

Section 112 of the Act, 15 U.S.C. 2312, provides that the Act shall apply only to those consumer products manufactured after July 4, 1975.\* \* \*

■ 4. Amend § 700.3 by revising the fourth and sixth sentences and footnote 1 of paragraph (a), the first sentence of paragraph (b), and the sixth sentence of paragraph (c) to read as follows:

# § 700.3 Written warranty.

- (a) \* \* \* Section 101(6), 15 U.S.C. 2301(6), provides that a written affirmation of fact or a written promise of a specified level of performance must relate to a specified period of time in order to be considered a "written warranty." \* \* \* In addition, section 111(d), 15 U.S.C. 2311(d), exempts from the Act (except section 102(c), 15 U.S.C. 2302(c)) any written warranty the making or content of which is required by federal law. \* \*
- (b) Certain terms, or conditions, of sale of a consumer product may not be "written warranties" as that term is defined in section 101(6), 15 U.S.C. 2301(6), and should not be offered or described in a manner that may deceive consumers as to their enforceability under the Act.\* \* \*

- (c) \* \* \* Such warranties are not subject to the Act, since a written warranty under section 101(6) of the Act, 15 U.S.C. 2301(6), must become "part of the basis of the bargain between a supplier and a buyer for purposes other than resale." \* \* \*
- 5. Amend § 700.4 by revising the first sentence to read as follows:

# § 700.4 Parties "actually making" a written warranty.

Section 110(f) of the Act, 15 U.S.C. 2310(f), provides that only the supplier "actually making" a written warranty is liable for purposes of FTC and private enforcement of the Act.\* \*

■ 6. Amend § 700.5 by revising paragraph (a) and the first and second sentences of paragraph (b) to read as follows:

### § 700.5 Expressions of general policy.

- (a) Under section 103(b), 15 U.S.C. 2303(b), statements or representations of general policy concerning customer satisfaction which are not subject to any specific limitation need not be designated as full or limited warranties, and are exempt from the requirements of sections 102, 103, and 104 of the Act, 15 U.S.C. 2302–2304, and rules thereunder. However, such statements remain subject to the enforcement provisions of section 110 of the Act, 15 U.S.C. 2310, and to section 5 of the Federal Trade Commission Act, 15 U.S.C. 45.
- (b) The section 103(b), 15 U.S.C. 2303(b), exemption applies only to general policies, not to those which are limited to specific consumer products manufactured or sold by the supplier offering such a policy. In addition, to qualify for an exemption under section 103(b), 15 U.S.C. 2303(b), such policies may not be subject to any specific limitations.\* \* \*
- 7. Amend § 700.6 by revising the first sentence of paragraph (a) and the first, second, and fourth sentences of paragraph (b) to read as follows:

### § 700.6 Designation of warranties.

- (a) Section 103 of the Act, 15 U.S.C. 2303, provides that written warranties on consumer products manufactured after July 4, 1975, and actually costing the consumer more than \$10, excluding tax, must be designated either "Full (statement of duration) Warranty" or "Limited Warranty".\* \* \*
- (b) Based on section 104(b)(4), 15 U.S.C. 2304(b)(4), the duties under subsection (a) of section 104, 15 U.S.C. 2304, extend from the warrantor to each person who is a consumer with respect to the consumer product. Section 101(3), 15 U.S.C. 2301(3), defines a

- consumer as a buyer (other than for purposes of resale) of any consumer product, any person to whom such product is transferred during the duration of an implied or written warranty (or service contract) applicable to the product.\* \* \* However, where the duration of a full warranty is defined solely in terms of first purchaser ownership there can be no violation of section 104(b)(4), 15 U.S.C. 2304(b)(4), since the duration of the warranty expires, by definition, at the time of transfer.\* \* \*
- 8. Amend § 700.7 by revising the first sentence of paragraph (a) to read as follows:

## § 700.7 Use of warranty registration cards.

- (a) Under section 104(b)(1) of the Act, 15 U.S.C. 2304(b)(1), a warrantor offering a full warranty may not impose on consumers any duty other than notification of a defect as a condition of securing remedy of the defect or malfunction, unless such additional duty can be demonstrated by the warrantor to be reasonable.\* \* \*
- 9. Amend § 700.8 by revising the third sentence to read as follows:

#### § 700.8 Warrantor's decision as final.

- \* \* \* Such statements are deceptive since section 110(d) of the Act, 15 U.S.C. 2310(d), gives state and federal courts jurisdiction over suits for breach of warranty and service contract.
- 10. Amend § 700.9 by revising the first and third sentences to read as follows:

# § 700.9 Duty to install under a full warranty.

Under section 104(a)(1) of the Act, 15 U.S.C. 2304(a)(1), the remedy under a full warranty must be provided to the consumer without charge.\* \* \* However, this does not preclude the warrantor from imposing on the consumer a duty to remove, return, or reinstall where such duty can be demonstrated by the warrantor to meet the standard of reasonableness under section 104(b)(1), 15 U.S.C. 2304(b)(1).

■ 11. Amend § 700.10 by revising the section heading, paragraph (a), the first sentence in paragraph (b), and paragraph (c) to read as follows:

# § 700.10 Prohibited tying.

- (a) Section 102(c), 15 U.S.C. 2302(c), prohibits tying arrangements that condition coverage under a written warranty on the consumer's use of an article or service identified by brand, trade, or corporate name unless that article or service is provided without charge to the consumer.
- (b) Under a limited warranty that provides only for replacement of

<sup>&</sup>lt;sup>1</sup> A "written warranty" is also created by a written affirmation of fact or a written promise that the product is defect free, or by a written undertaking of remedial action within the meaning of section 101(6)(B), 15 U.S.C. 2301(6)(B).

defective parts and no portion of labor charges, section 102(c), 15 U.S.C. 2302(c), prohibits a condition that the consumer use only service (labor) identified by the warrantor to install the replacement parts.\* \*

(c) No warrantor may condition the continued validity of a warranty on the use of only authorized repair service and/or authorized replacement parts for non-warranty service and maintenance (other than an article of service provided without charge under the warranty or unless the warrantor has obtained a waiver pursuant to section 102(c) of the Act, 15 U.S.C. 2302(c)). For example, provisions such as, "This warranty is void if service is performed by anyone other than an authorized 'ABC' dealer and all replacement parts must be genuine 'ABC' parts," and the like, are prohibited where the service or parts are not covered by the warranty. These provisions violate the Act in two ways. First, they violate the section 102(c), 15 U.S.Č. 2302(c), ban against tving arrangements. Second, such provisions are deceptive under section 110 of the Act, 15 U.S.C. 2310, because a warrantor cannot, as a matter of law, avoid liability under a written warranty where a defect is unrelated to the use by a consumer of "unauthorized" articles or service. In addition, warranty language that implies to a consumer acting reasonably in the circumstances that warranty coverage requires the consumer's purchase of an article or service identified by brand, trade or corporate name is similarly deceptive. For example, a provision in the warranty such as, "use only an authorized 'ABC' dealer" or "use only 'ABC' replacement parts," is prohibited where the service or parts are not provided free of charge pursuant to the warranty. This does not preclude a warrantor from expressly excluding liability for defects or damage caused by "unauthorized" articles or service: nor does it preclude the warrantor from denying liability where the warrantor can demonstrate that the defect or damage was so caused.

- 12. Amend § 700.11 by:
- a. Revising the fourth and fifth sentences and adding a sixth sentence in paragraph (a); and
- b. Revising the first sentence of paragraph (b) and the first and second sentences of paragraph (c).

The revisions and addition read as follows:

# § 700.11 Written warranty, service contract, and insurance distinguished for purposes of compliance under the Act.

(a) \* \* \* The McCarran-Ferguson Act, 15 U.S.C. 1011 *et seq.*, provides

- that most federal laws (including the Magnuson-Moss Warranty Act) shall not be construed to invalidate, impair, or supersede any law enacted by any State for the purpose of regulating the business of insurance. While three specific laws are subject to a separate proviso, the Magnuson-Moss Warranty Act is not one of them. Thus, to the extent the Magnuson-Moss Warranty Act's service contract provisions apply to the business of insurance, they are effective so long as they do not invalidate, impair, or supersede a State law enacted for the purpose of regulating the business of insurance.
- (b) "Written warranty" and "service contract" are defined in sections 101(6) and 101(8) of the Act, 15 U.S.C. 2301(6) and 15 U.S.C. 2301(8), respectively.\* \* \*
- (c) A service contract under the Act must meet the definitions of section 101(8), 15 U.S.C. 2301(8). An agreement which would meet the definition of written warranty in section 101(6)(A) or (B), 15 U.S.C. 2301(6)(A) or (B), but for its failure to satisfy the basis of the bargain test is a service contract.\* \* \*

# PART 701—DISCLOSURE OF WRITTEN CONSUMER PRODUCT WARRANTY TERMS AND CONDITIONS

■ 13. The authority citation for part 701 continues to read as follows:

Authority: 15 U.S.C. 2302 and 2309.

■ 14. Amend § 701.1 by revising paragraph (d) to read as follows:

# § 701.1 Definitions.

\* \* \* \* \*

- (d) Implied warranty means an implied warranty arising under State law (as modified by sections 104(a) and 108 of the Act, 15 U.S.C. 2304(a) and 2308), in connection with the sale by a supplier of a consumer product.
- 15. Amend § 701.3 by revising paragraph (a)(7) to read as follows:

### § 701.3 Written warranty terms.

(a) \* \* \*

(7) Any limitations on the duration of implied warranties, disclosed on the face of the warranty as provided in section 108 of the Act, 15 U.S.C. 2308, accompanied by the following statement:

Some States do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

\* \* \* \* \*

# PART 703—INFORMAL DISPUTE SETTLEMENT PROCEDURES

■ 16. The authority citation for part 703 continues to read as follows:

Authority: 15 U.S.C. 2309 and 2310.

■ 17. Amend § 703.1 by revising paragraph (e) to read as follows:

#### § 703.1 Definitions.

\* \* \* \* \*

- (e) Mechanism means an informal dispute settlement procedure which is incorporated into the terms of a written warranty to which any provision of Title I of the Act applies, as provided in section 110 of the Act, 15 U.S.C. 2310.
- 18. Amend § 703.2 by revising the second sentence of paragraph (a) to read as follows:

### § 703.2 Duties of warrantor.

- (a) \* \* \* This paragraph (a) shall not prohibit a warrantor from incorporating into the terms of a written warranty the step-by-step procedure which the consumer should take in order to obtain performance of any obligation under the warranty as described in section 102(a)(7) of the Act, 15 U.S.C. 2302(a)(7), and required by part 701 of this subchapter.
- 19. Amend § 703.5 by revising paragraph (g)(2), the first sentence in paragraph (i), and the third sentence in paragraph (j) to read as follows:

# § 703.5 Operation of the Mechanism.

\* \* \* \* (g) \* \* \*

(2) The Mechanism's decision is admissible in evidence as provided in section 110(a)(3) of the Act, 15 U.S.C. 2310(a)(3); and

\* \* \* \* \*

- (i) A requirement that a consumer resort to the Mechanism prior to commencement of an action under section 110(d) of the Act, 15 U.S.C. 2310(d), shall be satisfied 40 days after notification to the Mechanism of the dispute or when the Mechanism completes all of its duties under paragraph (d) of this section, whichever occurs sooner. \* \* \*
- (j) \* \* \* In any civil action arising out of a warranty obligation and relating to a matter considered by the Mechanism, any decision of the Mechanism shall be admissible in evidence, as provided in section 110(a)(3) of the Act, 15 U.S.C. 2310(a)(3).

By direction of the Commission, Commissioner Ohlhausen dissenting. **Donald S. Clark**,

Secretary.

**Note:** The following dissent will not appear in the Code of Federal Regulations.

## Dissenting Statement of Commissioner Maureen K. Ohlhausen

I voted against the Commission's Final Revised Interpretations of the Magnuson-Moss Warranty Act (MMWA) Rule because it retains Rule 703.5(j)'s prohibition on pre-dispute mandatory binding arbitration.<sup>1</sup>

Since the last Rule review in 1997, two federal appellate courts have held that the MMWA does not prohibit binding arbitration.2 Noting the federal policy favoring arbitration expressed in the Federal Arbitration Act (FAA),3 these courts concluded that the MMWA's statutory language and legislative history did not overcome the presumption in favor of arbitration and that the purposes of the MMWA and the FAA were not in inherent conflict. The courts also declined to give the Commission's contrary interpretation Chevron deference.<sup>4</sup> Although some lower courts have reached a different conclusion, there is no circuit court precedent upholding the Commission's interpretation of the MMWA in Rule 703.5(j). Additionally, in several recent cases, the Supreme Court has indicated a strong preference for arbitration.5

The courts have sent a clear signal that the Commission's position that MMWA prohibits binding arbitration is no longer supportable. When faced with such a signal, the Commission should not reaffirm the rule in question. I therefore respectfully dissent.

[FR Doc. 2015–14065 Filed 7–17–15; 8:45 am]

#### BILLING CODE 6750-01-P

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# **Food and Drug Administration**

#### 21 CFR Part 16

[Docket No. FDA-2015-N-0011]

# Regulatory Hearing Before the Food and Drug Administration; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is updating an authority citation for the Code of Federal Regulations. This action is technical in nature and is intended to provide accuracy of the Agency's regulations.

**DATES:** This rule is effective July 20, 2015.

#### FOR FURTHER INFORMATION CONTACT:

Mary E. Kennelly, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4338, Silver Spring, MD 20993– 0002, 240–402–9577, FDASIAImplementationORA@ fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** In a previous rulemaking, the authority citation for 21 CFR part 16 was inadvertently altered to omit 28 U.S.C. 2112 and changed 21 U.S.C. 467f to 21 U.S.C. 467F. FDA is reversing those changes such that 28 U.S.C. 2112 and 21 U.S.C. 467f are included in the list of authority citations for 21 CFR part 16.

# List of Subjects in 21 CFR Part16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 16 is amended as follows:

# PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for 21 CFR part 16 is revised to read as follows:

**Authority:** 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

Dated: July 15, 2015.

### Leslie Kux,

Associate Commissioner for Policy. [FR Doc. 2015–17714 Filed 7–17–15; 8:45 am]

BILLING CODE 4164-01-P

### POSTAL REGULATORY COMMISSION

#### 39 CFR Part 3020

[Docket Nos. MC2010-21 and CP2010-36]

### **Update to Product Lists**

**AGENCY:** Postal Regulatory Commission. **ACTION:** Final rule.

**SUMMARY:** The Commission is updating the product lists. This action reflects a publication policy adopted by Commission order. The referenced policy assumes periodic updates. The updates are identified in the body of this document. The product lists, which is re-published in its entirety, includes these updates.

DATES: Effective date: July 20, 2015. Applicability dates: March 31, 2015, Parcel Return Service Contract 6 (MC2015-41 and CP2015-53); April 8, 2015, Priority Mail Contract 121 (MC2015-43 and CP2015-54); April 8, 2015, Parcel Select Contract 9 (MC2015-44 and CP2015-55); April 8, 2015, Priority Mail & First-Class Package Service Contract 3 (MC2015-45 and CP2015-56); April 21, 2015, Priority Mail Express & Priority Mail Contract 17 (MC2015–47 and CP2015–58); April 21, 2015, Priority Mail Contract 122 (MC2015-46 and CP2015-57); May 1, 2015, Priority Mail & First-Class Package Service Contract 4 (MC2015-48 and CP2015-60); May 12, 2015, Priority Mail Express & Priority Mail Contract 18 (MC2015-49 and CP2015-61); May 27, 2015, Global Expedited Package Services Contracts Non-Published Rates 6 (MC2015-23 and CP2015-65); May 28, 2015, Parcel Return Service Contract 7 (MC2015-50 and CP2015-72); May 28, 2015, Parcel Return Service Contract 8 (MC2015-51 and CP2015-73); June 9, 2015, Priority Mail Contract 124 (MC2015–53 and CP2015–81); June 9, 2015, Priority Mail Contract 123 (MC2015-52 and CP2015-80); June 16, 2015, Priority Mail Contract 125 (MC2015–54 and CP2015–82).

**FOR FURTHER INFORMATION CONTACT:** David A. Trissell, General Counsel, at 202–789–6800.

SUPPLEMENTARY INFORMATION: This document identifies updates to the product lists, which appear as 39 CFR Appendix A to Subpart A of Part 3020—Mail Classification Schedule. Publication of the updated product lists in the Federal Register is addressed in the Postal Accountability and Enhancement Act (PAEA) of 2006.

Authorization. The Commission process for periodic publication of updates was established in Docket Nos. MC2010–21 and CP2010–36, Order No. 445, April 22, 2010, at 8.

<sup>&</sup>lt;sup>1</sup>I do not object to the other final actions taken in this review.

<sup>&</sup>lt;sup>2</sup> See Walton v. Rose Mobile Homes, LLC, 298 F.3d 470 (5th Cir. 2002); Davis v. Southern Energy Homes, Inc., 305 F.3d 1268 (11th Cir. 2002).

<sup>&</sup>lt;sup>3</sup> 9 U.S.C. 1. See Shearson/Am. Express Inc. v. McMahon, 482 U.S. 220 (1987) (noting that the presumption of the FAA is that arbitration is preferable and Congress must clearly override that presumption if it is to be disregarded).

<sup>&</sup>lt;sup>4</sup> Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984) (holding that courts defer to an agency's interpretation of a statute if "(1) Congress has not spoken directly to the issue; and (2) the agency's interpretation 'is based on a permissible construction of the statute'").

<sup>&</sup>lt;sup>5</sup> See, e.g., Am. Express Co. v. Italian Colors Rest., 133 S. Ct. 2304 (2013), AT&T Mobility LLC v. Concepcion, 131 S. Ct. 1740 (2011).

<sup>&</sup>lt;sup>6</sup> See Davis, 305 F.3d at 1280 ("[T]he FTC's interpretation of the MMWA is unreasonable, and we decline to defer to the FTC regulations of the MMWA regarding binding arbitration in written warranties.").

Changes. The product lists are being updated by publishing a replacement in its entirety of 39 CFR Appendix A to Subpart A of Part 3020—Mail Classification Schedule. The following products are being added, removed, or moved within the product lists:

1. Parcel Return Service Contract 6 (MC2015–41 and CP2015–53) (Order No. 2421), added March 31, 2015.

2. Priority Mail Contract 121 (MC2015–43 and CP2015–54) (Order No. 2428), added April 8, 2015.

3. Parcel Select Contract 9 (MC2015–44 and CP2015–55) (Order No. 2429), added April 8, 2015.

4. Priority Mail & First-Class Package Service Contract 3 (MC2015–45 and CP2015–56) (Order No. 2430), added April 8, 2015.

5. Priority Mail Express & Priority Mail Contract 17 (MC2015–47 and CP2015–58) (Order No. 2447), added April 21, 2015.

6. Priority Mail Contract 122 (MC2015–46 and CP2015–57) (Order No. 2451), added April 21, 2015.

7. Priority Mail & First-Class Package Service Contract 4 (MC2015–48 and CP2015–60) (Order No. 2464), added May 1, 2015.

8. Priority Mail Express & Priority Mail Contract 18 (MC2015–49 and CP2015–61) (Order No. 2480), added May 12, 2015.

9. Global Expedited Package Services Contracts Non-Published Rates 6 (MC2015–23 and CP2015–65) (Order No. 2513), added May 27, 2015.

10. Parcel Return Service Contract 7 (MC2015–50 and CP2015–72) (Order No. 2515), added May 28, 2015.

11. Parcel Return Service Contract 8 (MC2015–51 and CP2015–73) (Order No. 2518), added May 28, 2015.

12. Priority Mail Contract 124 (MC2015–53 and CP2015–81) (Order No. 2534), added June 9, 2015.

13. Priority Mail Contract 123 (MC2015–52 and CP2015–80) (Order No. 2535), added June 9, 2015.

14. Priority Mail Contract 125 (MC2015–54 and CP2015–82) (Order No. 2542), added June 16, 2015.

The following negotiated service agreements have expired and are being deleted from the Mail Classification Schedule:

- 1. Discover Financial Services 1 (MC2011–19 and R2011–3) (Order No. 694).
- 2. Priority Mail Express Contract 10 (MC2011–12 and CP2011–48) (Order No. 640).
- 3. Parcel Return Service Contract 3 (MC2013–39 and CP2013–51) (Order No. 1672).
- 4. Parcel Return Service Contract 4 (MC2013–46 and CP2013–60) (Order No. 1711).

5. Priority Mail Contract 31 (MC2011–10 and CP2011–46) (Order No. 637).

6. Priority Mail Contract 32 (MC2011–11 and CP2011–47) (Order No. 639).

7. Priority Mail Contract 34 (MC2011-17 and CP2011-56) (Order No. 655).

8. Priority Mail Contract 35 (MC2011–18 and CP2011–57) (Order No. 656).

9. Priority Mail Contract 36 (MC2012–2 and CP2012–6) (Order No. 1170).

10. Priority Mail Contract 38 (MC2012–7 and CP2012–15) (Order No. 1197).

11. Priority Mail Contract 49 (MC2013–25 and CP2013–33) (Order No. 1607).

12. Priority Mail Contract 50 (MC2013–26 and CP2013–34) (Order No. 1608).

13. Priority Mail Contract 68 (MC2014–6 and CP2014–7) (Order No. 1893).

14. Priority Mail Contract 69 (MC2014–7 and CP2014–8) (Order No. 1895).

15. Priority Mail Express & Priority Mail Contract 15 (MC2014–3 and CP2014–3) (Order No. 1872).

16. Parcel Select Contract 1 (MC2011–16 and CP2011–53) (Order No. 686).

17. First-Class Package Service Contract 1 (MC2012–11 and CP2012–19) (Order No. 1339).

18. First-Class Package Service Contract 3 (MC2012–19 and CP2012–25) (Order No. 1355).

19. First-Class Package Service Contract 4 (MC2012–20 and CP2012–26) (Order No. 1356).

20. First-Class Package Service Contract 5 (MC2012–21 and CP2012–27) (Order No. 1357).

21. First-Class Package Service Contract 6 (MC2012–22 and CP2012–28) (Order No. 1358).

22. First-Class Package Service Contract 7 (MC2012–23 and CP2012–29) (Order No. 1359).

Updated product lists. The referenced changes to the product lists are incorporated into 39 CFR Appendix A to Subpart A of Part 3020—Mail Classification Schedule.

# List of Subjects in 39 CFR Part 3020

Administrative practice and procedure, Postal Service.

For the reasons discussed in the preamble, the Postal Regulatory Commission amends part 3020 of title 39 of the Code of Federal Regulations as follows:

# PART 3020—PRODUCT LISTS

■ 1. The authority citation for part 3020 continues to read as follows:

**Authority:** 39 U.S.C. 503; 3622; 3631; 3642; 3682.

■ 2. Revise Appendix A of Subpart A of Part 3020 to read as follows:

# Appendix A to Subpart A of Part 3020—Mail Classification Schedule

(An asterisk (\*) indicates an organizational class or group, not a Postal Service product.) Part A—Market Dominant Products

1000 Market Dominant Product List

First-Class Mail \*

Single-Piece Letters/Postcards Presorted Letters/Postcards Flats

Parcels

Outbound Single-Piece First-Class Mail International

Inbound Letter Post

Standard Mail (Commercial and Nonprofit)\*
High Density and Saturation Letters
High Density and Saturation Flats/Parcels
Carrier Route

Letters

Flats

Parcels

Every Door Direct Mail—Retail

Periodicals '

In-County Periodicals

Outside County Periodicals

Package Services \*

Alaska Bypass Service Bound Printed Matter Flats Bound Printed Matter Parcels Media Mail/Library Mail

Special Services \*

Ancillary Services

International Ancillary Services

Address Management Services

Caller Service

Credit Card Authentication

International Reply Coupon Service International Business Reply Mail Service

Money Orders Post Office Box Service

Customized Postage

Stamp Fulfillment Services

Negotiated Service Agreements \*

Domestic \*

Valassis Direct Mail, Inc. Negotiated Service Agreement

PHI Acquisitions, Inc. Negotiated Service Agreement

International\*

Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators

Inbound Market Dominant Exprés Service Agreement 1

Nonpostal Services \*

Alliances with the Private Sector to Defray Cost of Key Postal Functions Philatelic Sales

Market Tests \*

Part B—Competitive Products

2000 Competitive Product List

Domestic Products \*

Priority Mail Express

Priority Mail

Parcel Select

Parcel Return Service

First-Class Package Service

Standard Post

International Products \*

Outbound International Expedited Services

```
Inbound Parcel Post (at UPU rates)
                                                   Priority Mail Contract 87
                                                                                                   First-Class Package Service Contract 13
                                                                                                   First-Class Package Service Contract 14
  Outbound Priority Mail International
                                                  Priority Mail Contract 88
  International Priority Airmail (IPA)
                                                  Priority Mail Contract 89
                                                                                                   First-Class Package Service Contract 15
                                                                                                   First-Class Package Service Contract 16
  International Surface Air List (ISAL)
                                                   Priority Mail Contract 90
  International Direct Sacks—M-Bags
                                                                                                   First-Class Package Service Contract 17
                                                  Priority Mail Contract 91
  Outbound Single-Piece First-Class Package
                                                   Priority Mail Contract 92
                                                                                                   First-Class Package Service Contract 18
    International Service
                                                   Priority Mail Contract 93
                                                                                                   First-Class Package Service Contract 19
                                                                                                   First-Class Package Service Contract 20
Negotiated Service Agreements *
                                                  Priority Mail Contract 94
                                                  Priority Mail Contract 95
                                                                                                   First-Class Package Service Contract 21
Domestic *
                                                                                                   First-Class Package Service Contract 22
  Priority Mail Express Contract 8
                                                  Priority Mail Contract 96
                                                                                                   First-Class Package Service Contract 23
  Priority Mail Express Contract 11
                                                  Priority Mail Contract 97
                                                   Priority Mail Contract 98
                                                                                                   First-Class Package Service Contract 24
  Priority Mail Express Contract 12
                                                                                                   First-Class Package Service Contract 25
                                                   Priority Mail Contract 99
  Priority Mail Express Contract 13
                                                                                                   First-Class Package Service Contract 26
  Priority Mail Express Contract 14
                                                  Priority Mail Contract 100
  Priority Mail Express Contract 15
                                                                                                   First-Class Package Service Contract 27
                                                  Priority Mail Contract 101
                                                                                                   First-Class Package Service Contract 28
  Priority Mail Express Contract 16
                                                  Priority Mail Contract 102
                                                                                                   First-Class Package Service Contract 29
  Priority Mail Express Contract 17
                                                  Priority Mail Contract 103
  Priority Mail Express Contract 18
                                                                                                   First-Class Package Service Contract 30
                                                  Priority Mail Contract 104
                                                                                                   First-Class Package Service Contract 31
  Priority Mail Express Contract 19
                                                  Priority Mail Contract 105
                                                                                                   First-Class Package Service Contract 32
                                                   Priority Mail Contract 106
  Priority Mail Express Contract 20
                                                                                                   First-Class Package Service Contract 33
  Priority Mail Express Contract 21
                                                  Priority Mail Contract 107
                                                                                                   First-Class Package Service Contract 34
  Priority Mail Express Contract 22
                                                  Priority Mail Contract 108
                                                                                                   First-Class Package Service Contract 35
  Priority Mail Express Contract 23
                                                   Priority Mail Contract 109
                                                                                                   First-Class Package Service Contract 36
  Priority Mail Express Contract 24
                                                  Priority Mail Contract 110
                                                                                                   First-Class Package Service Contract 37
  Priority Mail Express Contract 25
                                                   Priority Mail Contract 111
                                                                                                   Priority Mail Express, Priority Mail & First-
  Parcel Return Service Contract 5
                                                   Priority Mail Contract 112
                                                                                                      Class Package Service Contract 1
  Parcel Return Service Contract 6
                                                   Priority Mail Contract 113
                                                                                                   Priority Mail Express, Priority Mail & First-
  Parcel Return Service Contract 7
                                                  Priority Mail Contract 114
                                                                                                     Class Package Service Contract 2
  Parcel Return Service Contract 8
                                                  Priority Mail Contract 115
                                                                                                   Priority Mail Express, Priority Mail & First-
  Priority Mail Contract 24
                                                   Priority Mail Contract 116
                                                                                                     Class Package Service Contract 3
  Priority Mail Contract 29
                                                  Priority Mail Contract 117
                                                                                                   Priority Mail Express, Priority Mail & First-
  Priority Mail Contract 33
                                                   Priority Mail Contract 118
                                                                                                      Class Package Service Contract 4
  Priority Mail Contract 39
                                                   Priority Mail Contract 119
                                                                                                   Priority Mail & First-Class Package Service
  Priority Mail Contract 40
                                                  Priority Mail Contract 120
                                                                                                     Contract 1
  Priority Mail Contract 41
                                                  Priority Mail Contract 121
                                                                                                   Priority Mail & First-Class Package Service
  Priority Mail Contract 42
                                                  Priority Mail Contract 122
                                                                                                     Contract 2
  Priority Mail Contract 43
                                                  Priority Mail Contract 123
                                                                                                   Priority Mail & First-Class Package Service
  Priority Mail Contract 44
                                                  Priority Mail Contract 124
                                                                                                      Contract 3
  Priority Mail Contract 45
                                                  Priority Mail Contract 125
                                                                                                   Priority Mail & First-Class Package Service
  Priority Mail Contract 46
                                                   Priority Mail Express & Priority Mail
                                                                                                      Contract 4
  Priority Mail Contract 47
                                                     Contract 9
                                                                                                 Outbound International *
  Priority Mail Contract 48
                                                   Priority Mail Express & Priority Mail
                                                                                                   Global Expedited Package Services (GEPS)
  Priority Mail Contract 51
                                                     Contract 10
                                                                                                     Contracts
  Priority Mail Contract 52
                                                  Priority Mail Express & Priority Mail
                                                                                                    GEPS 3
  Priority Mail Contract 53
                                                     Contract 11
                                                                                                   Global Direct Contracts
  Priority Mail Contract 54
                                                  Priority Mail Express & Priority Mail
                                                                                                   Global Direct Contracts 1
  Priority Mail Contract 55
                                                     Contract 12
                                                                                                   Global Bulk Economy (GBE) Contracts
  Priority Mail Contract 56
                                                   Priority Mail Express & Priority Mail
                                                                                                   Global Plus Contracts
  Priority Mail Contract 57
                                                     Contract 13
                                                                                                   Global Plus 1C
  Priority Mail Contract 58
                                                  Priority Mail Express & Priority Mail
                                                                                                   Global Plus 2C
  Priority Mail Contract 59
                                                     Contract 14
                                                                                                   Global Reseller Expedited Package
  Priority Mail Contract 60
                                                   Priority Mail Express & Priority Mail
  Priority Mail Contract 61
                                                     Contract 16
                                                                                                   Global Reseller Expedited Package Services
  Priority Mail Contract 62
                                                   Priority Mail Express & Priority Mail
  Priority Mail Contract 63
                                                     Contract 17
                                                                                                   Global Reseller Expedited Package Services
  Priority Mail Contract 64
                                                  Priority Mail Express & Priority Mail
  Priority Mail Contract 65
                                                     Contract 18
                                                                                                   Global Reseller Expedited Package Services
  Priority Mail Contract 66
                                                  Parcel Select & Parcel Return Service
  Priority Mail Contract 67
                                                     Contract 3
                                                                                                   Global Reseller Expedited Package Services
  Priority Mail Contract 70
                                                   Parcel Select & Parcel Return Service
  Priority Mail Contract 71
                                                     Contract 5
                                                                                                   Global Expedited Package Services
  Priority Mail Contract 72
                                                   Parcel Select Contract 2
                                                                                                     (GEPS)—Non-Published Rates
  Priority Mail Contract 73
                                                  Parcel Select Contract 3
                                                                                                   Global Expedited Package Services
  Priority Mail Contract 74
                                                   Parcel Select Contract 4
                                                                                                      (GEPS)—Non-Published Rates 2
  Priority Mail Contract 75
                                                  Parcel Select Contract 5
                                                                                                   Global Expedited Package Services
  Priority Mail Contract 76
                                                  Parcel Select Contract 6
                                                                                                     (GEPS)—Non-Published Rates 3
  Priority Mail Contract 77
                                                   Parcel Select Contract 7
                                                                                                   Global Expedited Package Services
  Priority Mail Contract 78
                                                  Parcel Select Contract 8
                                                                                                     (GEPS)—Non-Published Rates 4
  Priority Mail Contract 79
                                                  Parcel Select Contract 9
                                                                                                   Global Expedited Package Services
                                                  Priority Mail—Non-Published Rates
Priority Mail—Non-Published Rates 1
  Priority Mail Contract 80
                                                                                                      (GEPS)—Non-Published Rates 5
  Priority Mail Contract 81
                                                                                                   Global Expedited Package Services
  Priority Mail Contract 82
                                                   First-Class Package Service Contract 8
                                                                                                     (GEPS)—Non-Published Rates 6
  Priority Mail Contract 83
                                                   First-Class Package Service Contract 9
                                                                                                   Priority Mail International Regional Rate
  Priority Mail Contract 84
                                                                                                     Boxes—Non-Published Rates
                                                   First-Class Package Service Contract 10
                                                  First-Class Package Service Contract 11
  Priority Mail Contract 85
                                                                                                   Outbound Competitive International
```

First-Class Package Service Contract 12

Merchandise Return Service

Priority Mail Contract 86

Agreement with Royal Mail Group, Ltd. Priority Mail International Regional Rate Boxes Contract 1

Inbound International\*

International Business Reply Service (IBRS) Competitive Contracts

International Business Reply Service Competitive Contract 1

International Business Reply Service Competitive Contract 3

Inbound Direct Entry Contracts with Customers

Inbound Direct Entry Contracts with Foreign Postal Administrations Inbound Direct Entry Contracts with Foreign Postal Administrations Inbound Direct Entry Contracts with

Foreign Postal Administrations 1
Inbound EMS

Inbound EMS

Inbound EMS 2

Inbound Air Parcel Post (at non-UPU rates) Royal Mail Group Inbound Air Parcel Post Agreement

Inbound Competitive Multi-Service Agreements with Foreign Postal Operators 1

Special Services \*

Address Enhancement Services Greeting Cards, Gift Cards, and Stationery International Ancillary Services International Money Transfer Service— Outbound

International Money Transfer Service— Inbound

Premium Forwarding Service Shipping and Mailing Supplies Post Office Box Service Competitive Ancillary Services

Nonpostal Services \*

Advertising

Licensing of Intellectual Property other than Officially Licensed Retail Products (OLRP)

Mail Service Promotion

Officially Licensed Retail Products (OLRP)

Passport Photo Service

Photocopying Service

Rental, Leasing, Licensing or other Non-Sale Disposition of Tangible Property Training Facilities and Related Services USPS Electronic Postmark (EPM) Program

Market Tests \*

Metro Post

International Merchandise Return Service (IMRS)—Non-Published Rates Customized Delivery

# Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015-17685 Filed 7-17-15; 8:45 am]

BILLING CODE 7710-FW-P

# ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R05-OAR-2013-0436; EPA-R05-OAR-2014-0663; FRL-9929-71-Region 5]

# Approval and Promulgation of Air Quality Implementation Plans; Illinois; Midwest Generation Variances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is approving into the Illinois regional haze State Implementation Plan (SIP) variances affecting the following Midwest Generation, LLC facilities: Crawford Generating Station (Cook County), Joliet Generating Station (Will County), Powerton Generating Station (Tazewell County), Waukegan Generating Station (Lake County), and Will County Generating Station (Will County). The Illinois Environmental Protection Agency (IEPA) submitted these variances to EPA for approval on May 16, 2013, and August 18, 2014.

**DATES:** This final rule is effective on August 19, 2015.

**ADDRESSES:** EPA has established dockets for this action under Docket ID Nos. EPA-R05-OAR-2013-0436 and EPA-R05-OAR-2014-0663. All documents in the docket are listed on the www.regulations.gov Web site. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Kathleen D'Agostino, Environmental Engineer, at (312) 886-1767 before visiting the Region 5 office.

## FOR FURTHER INFORMATION CONTACT:

Kathleen D'Agostino, Environmental Engineer, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–1767, dagostino.kathleen@epa.gov.

#### SUPPLEMENTARY INFORMATION:

Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

I. What is the background for this action? II. What action is EPA taking? III. Incorporation by reference IV. Statutory and Executive Order Reviews.

# I. What is the background for this action?

On June 24, 2011, Illinois submitted a plan to address the requirements of the Regional Haze Rule, as codified at 40 CFR 51.308. EPA approved Illinois regional haze SIP on July 6, 2012 (77 FR 39943). Among the rules approved in this action to meet the best available retrofit technology (BART) requirements of the Regional Haze Rule are Illinois Administrative Code rules: 35 Ill. Adm. Code 225.292: "Applicability of the Combined Pollutant Standard;" 35 Ill. Adm. Code 225.295 "Combined Pollutant Standard: Emissions Standards for NO<sub>X</sub> and SO<sub>2</sub>;" 35 Ill. Adm. Code 225.296 "Combined Pollutant Standard: Control Technology Requirements for NO<sub>X</sub>, SO<sub>2</sub>, and PM Emissions" (except for paragraph 225.296(d)); and 35 Ill. Adm. Code 225 Appendix A, which identifies the Midwest Generation Electric Generating Units (EGUs) specified for purposes of the combined pollutant standard (CPS).

The Illinois Pollution Control Board (IPCB) granted Midwest Generation variances to Section 225.296(a)(1) and 225.296(c)(1) on August 23, 2012, and to Section 225.295(b) and Section 225.296(a)(2) on April 4, 2013. IEPA submitted these variances as revisions to the Illinois regional haze SIP on May 16, 2013, and August 18, 2014. EPA proposed to approve these variances on April 23, 2015 (80 FR 22662). EPA received no comments on the proposed action

II. What action is EPA taking?

EPA is finalizing approval of the Midwest Generation variances submitted by IEPA on May 16, 2013, and August 18, 2014, as revisions to the Illinois regional haze SIP.

# III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Illinois Regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these

documents generally available electronically through www.regulations.gov and/or in hard copy at the appropriate EPA office (see the ADDRESSES section of this preamble for more information).

### IV. Statutory and Executive Order Reviews

Under the Clean Air Act (CAA), the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999):
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land

or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small **Business Regulatory Enforcement** Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 18, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

## List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: June 19, 2015.

# Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

# PART 52—APPROVAL AND PROMULGATION OF **IMPLEMENTATION PLANS**

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

■ 2. Section 52.720 is amended by adding paragraph (c)(205) to read as follows:

# § 52.720 Identification of plan.

\*

\* (c) \* \* \*

(205) On May 16, 2013, and August 18, 2014, Illinois submitted variances to its regional haze state implementation plan affecting the following Midwest Generation, LLC facilities: Crawford Generating Station (Cook County), Joliet Generating Station (Will County), Powerton Generating Station (Tazewell County), Waukegan Generating Station (Lake County), and Will County Generating Station (Will County).

(i) Incorporation by Reference. (A) Illinois Pollution Control Board Order PCB 12-121, adopted on August 23, 2012; Certificate of Acceptance, dated August 24, 2012, filed with the Illinois Pollution Control Board Clerk's Office August 27, 2012

(B) Illinois Pollution Control Board Order PCB 13-24, adopted on April 4, 2013; Certificate of Acceptance, dated May 16, 2013, filed with the Illinois Pollution Control Board Clerk's Office May 17, 2013.

[FR Doc. 2015-17662 Filed 7-17-15; 8:45 am] BILLING CODE 6560-50-P

### **ENVIRONMENTAL PROTECTION AGENCY**

#### 40 CFR Part 52

[EPA-R06-OAR-2013-0542; FRL-9930-44-Region-6]

Approval and Promulgation of Implementation Plans; Texas; **Revisions to the New Source Review** State Implementation Plan; Flexible **Permit Program** 

**AGENCY:** Environmental Protection Agency (EPA). **ACTION:** Final rule.

**SUMMARY:** The EPA is fully approving revisions to the Texas New Source Review (NSR) State Implementation Plan (SIP) to establish the Texas Minor NSR Flexible Permits Program (FPP), submitted by the Texas Commission on Environmental Quality (TCEQ). The approval was predicated on the TCEQ meeting its commitment outlined in its letter dated December 9, 2013, to adopt certain minor clarifications to the Flexible Permit Program (FPP) by November 30, 2014. The TCEQ submitted the revised program rules to meet its commitment on July 31, 2014. The EPA is finalizing this action under section 110 of the Clean Air Act (CAA). **DATES:** This final rule will be effective August 19, 2015.

ADDRESSES: The EPA has established a docket for this action under Docket ID

No. EPA-R06-OAR-2013-0542. All documents in the docket are listed in the http://www.regulations.gov index. Although listed in the index, some information is not publicly available. E.g., Confidential Business Information or other information the disclosure of which is restricted by the statute. Certain other material such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in http:// www.regulations.gov or in hard copy at the Air Permits Section (6PD-R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202-2733. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available at either location (e.g., CBI).

**FOR FURTHER INFORMATION CONTACT:** Ms. Stephanie Kordzi, telephone 214–665–7520; email address *kordzi.stephanie@epa.gov.* 

# SUPPLEMENTARY INFORMATION:

Throughout this document whenever "we," "us," or "our" is used, we mean the EPA.

### **Table of Contents**

I. Background
II. Response to Comments
III. When is this action effective?
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VI. Statutory and Executive Order Reviews

#### I. Background

On July 14, 2014, the EPA took final rulemaking action conditionally approving revisions to the Texas NSR SIP to establish the Texas Minor NSR Flexible Permits Program, submitted by the TCEQ. The EPA's proposed conditional approval was published in 79 FR 8368, February 12, 2014. The conditional approval was predicated on a commitment from TCEQ in a letter dated December 9, 2013, to adopt certain minor clarifications to the FPP by November 30, 2014. (79 FR 40666, July 14, 2014).

On September 12, 2014, Environmental Integrity Project, et al., filed a Petition for Review challenging the EPA conditional approval of the FPP with the Fifth Circuit Court of Appeals. The U.S. Department of Justice submitted the response to the Petition, Case No. 14–60649, for the EPA on March 2, 2015. The Appeal is on-going as of the date of publication of this notice.

On July 31, 2014, the TCEQ submitted revisions to the Texas NSR SIP. The

rulemaking properly structured the rules within and according to the rulemaking requirements of the Texas Administrative Procedure Act and the Texas Administrative Code. The EPA proposed full approval of the FPP (79 FR 7875, December 31, 2014) based on its determination that the SIP revisions complied with section 110(k) of the Federal Clean Air Act (the Act or CAA) and was consistent with the EPA's regulations and policies. These revisions supported this action to convert the approved conditional FPP to a fully approved FPP. The EPA reopened the public notice period for an additional 30 days (80 FR 21199, April 17, 2015), due to items being inadvertently omitted from the docket during the public notice period beginning December 31, 2014.

#### II. Response to Comments

The EPA proposed an initial comment period of 30 days. We received comments from 3 organizations during the initial comment period as follows: The TCEQ, Baker Botts, and the Environmental Integrity Project (EIP) on behalf of the Environmental Justice Advocacy Services, Community in Power & Development Association, Citizens for Environmental Justice, Air Alliance Houston, Texas Campaign for the Environment, and the Texas Impact. All comments previously submitted under the first public notice for this action are being responded to as appropriate and the commenters were informed that they did not need to resubmit them during the reopened public notice period. The EPA did not receive any additional comments during the reopened public notice period. All comment letters can be found in their entirety in the docket for this rulemaking.

Comment 1: Baker Botts stated they supported EPA's proposed approval of the Texas FPP. They believe it complies with the federal Clean Air Act. Further they believe that flexible permits are an essential part of the Texas air quality permitting program and the program has contributed to marked and sustained improvements in Texas air quality. They submitted information from TCEQ's Web site which documents reductions in ozone and other pollutants in Texas.

Response 1: The EPA appreciates the support for our final approval. No changes were made to the final rule as a result of this comment.

Comment 2: The TCEQ concurs with the EPA's proposed determination that the TCEQ fulfilled its December 9, 2013, commitment to submit the FPP SIP revision. The TCEQ also concurs with EPA's proposed finding that the TCEQ has satisfied all the elements of the EPA's final conditional approval (79 FR 40666, July 14, 2014). The TCEQ submitted on July 31, 2014, the following rules: 30 TAC Sections 116.13, 116.710, 116.711(1), (2)(A)(B) and (C)(i) and (ii), (D)–(J), and (L)–(N); 116.715(a)–(e) and (f)(1) and (2)(B); 116.716; 116.717; 116.718; 116.721; and 116.765.

Response 2: The EPA appreciates the support for our final approval of the rule. No changes were made to the final rule as a result of this comment.

Comment 3: The EIP stated the following: "this full approval action is non-substantive, it is not the agency action we seek to, or intend to, challenge." EIP did resubmit their April 4, 2014, comments on the proposed conditional approval (Attachment A), and their January 27, 2015, Fifth Circuit Court of Appeals brief (Attachment B).

Response 3: The EIP did not submit comments on the substance of this action, which addressed the rules being properly structured within and according to the rulemaking requirements of the Texas Administrative Procedure Act and the Texas Administrative Code. The EPA addressed the April 4, 2014, comments that the EIP resubmitted in its response to comments contained in the final conditional approval. (79 FR 40666, July 14, 2014). Further, the Brief of Respondent U.S. Environmental Protection Agency, Case No. 14-60649, filed on March 2, 2015, replies to the issues raised by EIP in its January 27, 2015, Fifth Circuit Court of Appeals brief. EPA is incorporating by reference the EPA's Reply Brief in this response to the EIP's resubmitted comments. It can be found in the Docket to this action.

# III. When is this action effective?

The EPA has determined that today's final approval of the Texas FPP is subject to the requirement to delay a rule's effective date until 30 days after publication in 5 U.S.C. 553(d) of the APA; therefore, the rule, will become effective 30 days after publication.

# **IV. Final Action**

After careful consideration of submitted revisions to meet the requirements of the conditional approval and of the comments received and the responses to each comment provided above, and under section 110 of the Act, the EPA is finalizing our proposal to convert the conditional approval of the FPP to a full, final action. Further, we have found it complies with section 110(l) of the Act.

We are making the following revisions to the Texas SIP:

- Revisions to 30 TAC Section 116.13—Flexible Permit Definitions.
- Revisions to 30 TAC Section 116.710—Applicability.
- Revisions to 30 TAC Section 116.711(1), (2)(A), (B) and (C)(i) and (ii), (D)–(J), and (L)–(N)—Flexible Permit Application.
- Revisions to 30 TAC Section 116.715(a)–(e) and (f)(1) and (2)(B)—General and Special Conditions.
- Revisions to 30 TAC Section 116.716—Emission Caps and Individual Emission Limitations.
- Revisions to 30 TAC Section 116.717—Implementation Schedule for Additional Controls.
- Revisions to 30 TAC Section 116.718—Significant Emission Increase.
- Revisions to 30 TAC Section 116.720—Limitation of Physical and Operational Changes.
- Revisions to 30 TAC Section
   116.721—Amendments and Alterations.
- Revisions to 30 TAC Section 116.740(a)—Public Notice.
- Revisions to 30 TAC Section 116.750—Flexible Permit Fee. Revisions to 30 TAC Section 116.765— Compliance Schedule.

The EPA has determined that the revised rule satisfies the December 9, 2013, Commitment Letter which was submitted in a timely manner.

### V. Incorporation by Reference

In this rule, we are finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, we are finalizing the incorporation by reference of the revisions to the Texas regulations as described in the Final Action section above. We have made, and will continue to make, these documents generally available electronically through www.regulations.gov and/or in hard copy at the EPA Region 6 office.

# VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. See, 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond

those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the

Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 18, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposed of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: June 30, 2015.

# Ron Curry,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

# PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

# Subpart SS—Texas

■ 2. In § 52.2270(c), the table titled "EPA Approved Regulations in the Texas SIP" is amended by revising the entries for sections 116.13, 116.710, 116.711, 116.715, 116.716, 116.717, 116.718, 116.720, 116.721, 116.740, 116.750, and 116.765 to read as follows:

### § 52.2270 Identification of plan.

(c) \* \* \* \* \* \*

	EPA Appro	VED REGULAT	TIONS IN THE TEXA	AS SIP				
State citation	Title/Subject	State approval/ EPA Approval date Submittal date			Explanation			
*	* *	*	*			*	*	
	Chapter 116 (Reg 6)—Control of	Air Pollution by	Permits for New Co	onstructio	on or I	Modification		
		Subchapter A-	-Definitions					
*	* *	*	*			*	*	
Section 116.13	Flexible Permit Definitions	7/31/2014	7/20/2015 [Insert ister citation].	Federal	Reg-			
*	* *	*	*			*	*	
	Si	ubchapter G—F	lexible Permits					
Section 116.710	Applicability	7/31/2014	7/20/2015 [Insert	Federal	Reg-			
Section 116.711	Flexible Permit Application	7/31/2014	ister citation]. 7/20/2015 [Insert ister citation].	Federal	Reg-	SIP includes (2)(A), (B) (D)-(J), and	and (C)(i) a	
*	* *	*	*		_	*	*	
Section 116.715	General and Special Conditions		7/20/2015 [Insert ister citation].		_	SIP includes 3 (e) and (f)(1	30 TAC 116.7 ) and (2)(B)	′15(a)–
Section 116.716	Emission Caps and Individual Emission Limitations.	7/31/2014	7/20/2015 [Insert ister citation].	Federal	Reg-			
	Implementation Schedule for Additional Controls.		7/20/2015 [Insert ister citation].		_			
Section 116.718	Significant Emission Increase	7/31/2014	7/20/2015 [Insert ister citation].	Federal	Reg-			
Section 116.720	Limitation on Physical and Operational Changes.	7/31/2014	7/20/2015 [Insert ister citation].	Federal	Reg-			
Section 116.721	Amendments and Alterations	7/31/2014	7/20/2015 [Insert ister citation].	Federal	Reg-			
*	* *	*	*			*	*	
Section 116.740	Public Notice and Comment	7/31/2014	7/20/2015 [Insert ister citation].	Federal	Reg-	SIP includes 116.740(a).	30 TAC 5	Section
Section 116.750	Flexible Permit Fee	7/31/2014	7/20/2015 [Insert ister citation].	Federal	Reg-			
*	* *	*	*		_	*	*	
Section 116.765	Compliance Schedule	7/31/2014	7/20/2015 [Insert ister citation].	Federal	Reg-	SIP includes 116.765(b)		Section
*	* *	*	*			*	*	

[FR Doc. 2015–17472 Filed 7–17–15; 8:45 am] BILLING CODE 6560–50–P

# ENVIRONMENTAL PROTECTION AGENCY

# 40 CFR Part 52

[EPA-R06-OAR-2015-0027; FRL-9930-79-Region-6]

Approval and Promulgation of Implementation Plans; Texas; Low Reid Vapor Pressure Fuel Regulations

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

SUMMARY: The EPA is taking a direct final action to approve revisions to the Texas State Implementation Plan (SIP) related to Low Reid Vapor Pressure (RVP) Fuel Regulations that were submitted by the State of Texas on January 5, 2015. The EPA evaluated the SIP submittal from Texas and determined these revisions are consistent with the requirements of the Clean Air Act (Act or CAA). The EPA is approving this action under the federal CAA.

**DATES:** This direct final rule is effective on September 18, 2015 without further notice, unless the EPA receives relevant

adverse comment August 19, 2015. If the EPA receives such comment, the EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R06-OAR-2015-0027, by one of the following methods:

- (1) www.regulations.gov: Follow the on-line instructions.
- (2) Email: Ms. Tracie Donaldson at donaldson.tracie@epa.gov.
- (3) Mail or Delivery: Ms. Tracie Donaldson, Air Permits Section (6PD– R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

Instructions: Direct your comments to Docket ID No. EPA-R06-OAR-2015-0027. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at http:// www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information through http://www.regulations.gov or email, if you believe that it is CBI or otherwise protected from disclosure. The http://www.regulations.gov Web site is an "anonymous access" system, which means that the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through http:// www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment along with any disk or CD-ROM submitted. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption and should be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at http://www.epa.gov/ epahome/dockets.htm.

Docket: The index to the docket for this action is available electronically at www.regulations.gov and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available at either location (e.g., CBI).

#### FOR FURTHER INFORMATION CONTACT: Ms.

Tracie Donaldson, (214) 665–6633, donaldson.tracie@epa.gov. To inspect the hard copy materials, please schedule an appointment with Ms. Donaldson or Mr. Bill Deese at 214–665–7253.

#### SUPPLEMENTARY INFORMATION:

Throughout this document wherever "we," "us," or "our" is used, we mean the EPA.

### I. Background

# A. CAA and SIPs

Section 110 of the CAA requires states to develop and submit to the EPA a SIP to ensure that state air quality meets National Ambient Air Quality Standards (NAAQS). The NAAQS currently address six criteria pollutants: Carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide. Each federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin through air pollution regulations and control strategies. The EPAapproved SIP provisions and control strategies are federally enforceable. States revise the SIP as needed and submit revisions to the EPA for review and approval.

B. SIP Revision Submitted on January 5, 2015

On September 10, 2014, Texas Commission on Environmental Quality (TCEQ) adopted revisions to 30 Texas Administrative Code (TAC) Chapter 114, Control of Air Pollution from Motor Vehicles, Subchapter H. Low Emission Fuels, Division 1. Gasoline Volatility. This review will determine if the changes to the Texas SIP are consistent with the requirements of the Clean Air Act and EPA's policy and guidance.

# II. EPA's Evaluation

As detailed in the Technical Support Document (TSD) accompanying this action, the TCEQ submitted a SIP revision to the Low RVP Fuels regulations. In this adoption, TCEQ amended sections 114.306, 114.307, 114.309 and deleted section 114.304. The amendments to the Regional Low **RVP** Gasoline Regulations remove obsolete requirements that provide no benefit to the state and are not necessary for the implementation and enforcement of the primary gasoline volatility control requirements of the rule. In addition, the proposal would provide regulatory consistency between the Chapter 114 gasoline volatility requirements and the El Paso Low RVP Gasoline requirements, specified in the 30 TAC Chapter 115 regulations in §§ 115.252, 115.253, 115.255–115.257, and 115.259, which do not prohibit the use of MTBE and do not require registration and annual reporting.

In addition, pursuant to section 110(k)(6) of the CAA, 30 TAC section 114.306(c) is being removed from the SIP. This section was inadvertently approved into the SIP by a previous action. In its April 25, 2000 SIP submittal, Texas specifically asked us to not include 114.306(c) into the SIP, but

we included it in the SIP on April 26, 2001 (66 FR 20927, 20931). Our action today corrects this error by removing section 114.306(c) from the SIP.

The amendments remove the prohibition on the increased use of methyl-tertiary-butyl-ether (MTBE) in gasoline to conform to the low RVP gasoline requirements; remove the requirements for gasoline producers and importers that supply low RVP gasoline to the affected counties; remove annual reporting and certification requirements on the use of MTBE in low RVP gasoline; and make other nonsubstantive clarifying changes as needed for accuracy and consistency.

### **III. Final Action**

For the reasons stated above and in the TSD, the EPA is taking direct final action to approve revisions to the Texas SIP pertaining to Low RVP Fuel regulations. We are approving the revisions to the Texas SIP under section 110 of the Act. Each revision to an implementation plan submitted by a State under this chapter shall be adopted by such State after reasonable notice and public hearing. The Administrator shall not approve a revision of a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress. We are publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no relevant adverse comments. However, in the proposed rules section of this Federal Register publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if relevant adverse comments are received. This rule will be effective on September 18, 2015 without further notice unless we receive relevant adverse comment by August 19, 2015. If we receive relevant adverse comments, we will publish a timely withdrawal in the Federal **Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so now. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

# IV. Incorporation by Reference

In this direct final rule, the EPA is finalizing regulatory text that includes

incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Texas low RVP fuel requirements described in the Final Action section above. The EPA has made, and will continue to make, these documents generally available electronically through <a href="https://www.regulations.gov">www.regulations.gov</a> and/or in hard copy at the EPA Region 6 office.

# V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small **Business Regulatory Enforcement** Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a

"major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 18, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposed of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

## List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: July 7, 2015.

#### Ron Curry

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

# PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

# Subpart SS—Texas

■ 2. In § 52.2270(c), the table titled "EPA Approved Regulations in the Texas SIP" is amended by removing the entry for section 114.304 and revising the entries for sections 114.306, 114.307 and 114.309 to read as follows:

# § 52.2270 Identification of plan. \* \* \* \* \* \* (c) \* \* \*

### EPA APPROVED REGULATIONS IN THE TEXAS SIP

State citation	Title/Subject	State approval/ submittal date		EPA approval date		Explanation		
*	*	*	*	*	*	*		

Chapter 114—Control of Air Pollution From Motor Vehicle Fuels

EPA APPROVED	REGULATIONS	IN THE	TEXAS	SIP—	Continued

State citation	Title/Subject	State approval/ submittal date	EPA approval date			Explanation	
*	*	*	*	*	*	*	
		Subcha	pter H—Low Emissio	n Fuels			
		Divi	sion 1: Gasoline Vola	tility			
*	*	*	*	*	*	*	
114.306	Recordkeeping Requirements.	4/25/2000	4/26/2001, 66 FR 20	927		Not in SIP: 114.306(c)	
114.307	Exemptions	9/10/2014	7/20/2015, [Insert Fe	deral Register cit	ation]		
	Affected Counties		7/20/2015, [Insert <b>Fe</b>				
*	*	*	*	*	*	*	

[FR Doc. 2015-17743 Filed 7-17-15; 8:45 am] BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

#### 40 CFR Part 52

[EPA-R04-OAR-2015-0368; FRL-9930-76-Region 41

Approval and Promulgation of Implementation Plans; North Carolina; Nitrogen Dioxide and Sulfur Dioxide **National Ambient Air Quality Standards Changes** 

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is taking direct final action to approve the State Implementation Plan (SIP) revision submitted by the State of North Carolina, through the North Carolina Department of Environment and Natural Resources on August 13, 2012, pertaining to definition changes for the Nitrogen Dioxide (NO<sub>2</sub>) and Sulfur Dioxide (SO<sub>2</sub>) National Ambient Air Quality Standards (NAAQS). EPA is approving this SIP revision because the State has demonstrated that it is consistent with the Clean Air Act (CAA or Act).

**DATES:** This direct final rule is effective on September 18, 2015 without further notice, unless EPA receives relevant adverse comment by August 19, 2015. If EPA receives such comment, EPA will publish a timely withdrawal in the Federal Register informing the public that this rule will not take effect. **ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R04OAR-2015-0368, by one of the following methods:

- 1. www.regulations.gov: Follow the on-line instructions for submitting comments.
  - Email: R4-ARMS@epa.gov.
  - 3. Fax: 404-562-9019.
- 4. Mail: "EPA-R04-OAR-2015-0368" Air Regulatory Management Section (formerly the Regulatory Development Section), Air Planning and Implementation Branch (formerly the Air Planning Branch), Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960.
- 5. Hand Delivery or Courier: Lynorae Benjamin, Chief, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. "EPA-R04-OAR-2015-0368". EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through www.regulations.gov or email, information that you consider to be CBI or otherwise protected. The www.regulations.gov Web site is an

"anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at http:// www.epa.gov/epahome/dockets.htm.

Docket: All documents in the electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. EPA

requests that if at all possible, you contact the person listed in the FOR FURTHER INFORMATION CONTACT section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Zuri Farngalo, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9152. Mr. Farngalo can be reached via electronic mail at farngalo.zuri@epa.gov.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

Sections 108 and 109 of the CAA govern the establishment, review, and revision, as appropriate, of the NAAQS to protect public health and welfare. The CAA requires periodic review of the air quality criteria—the science upon which the standards are based—and the standards themselves. EPA's regulatory provisions that govern the NAAQS are found at 40 CFR 50-National Primary and Secondary Ambient Air Quality Standards. In this rulemaking, EPA is proposing to approve North Carolina's August 13, 2012, submission amending the State's NAAQS for NO2 and SO2 that are found at 15A NCAC 02D .0407 and .0402. The SIP submittal amending North Carolina's rules to incorporate the NAAQS can be found in the Docket for this proposed rulemaking at www.regulations.gov and are summarized below.

# II. EPA's Analysis of North Carolina's SIP Revision

 $A. NO_2$ 

On February 9, 2010, EPA promulgated a new 1-hour primary NAAOS for NO<sub>2</sub> at a level of 100 parts per billion (ppb), based on a 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. See 75 FR 6474. Accordingly, in the August 3, 2012, SIP submission, North Carolina revised state rule 15A NCAC 02D .0407 Nitrogen Dioxide to update the primary air quality standard for NO2 to be consistent with the NAAQS that were promulgated by EPA in 2010. EPA has reviewed this change to North Carolina's rule for NO<sub>2</sub> and has made the determination that this change is consistent with federal regulations.

 $B. SO_2$ 

On June 22, 2010, EPA promulgated a revised primary SO<sub>2</sub> NAAQS to an hourly standard of 75 ppb based on a 3year average of the annual 99th percentile of 1-hour daily maximum concentrations. See 75 FR 35520. Accordingly, in the August 3, 2012, SIP submission, North Carolina revised state rule 15A NCAC 02D .0402 Sulfur Oxides to update the primary air quality standard for  $SO_2$  to be consistent with the SO<sub>2</sub> NAAQS that were promulgated by EPA in 2010. EPA has reviewed the change to North Carolina's rule for SO<sub>2</sub> and has made the determination that these changes are consistent with federal regulations.

# III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporate by reference of NCDENR regulations 15A NCAC 02D .0407 Nitrogen Dioxide and 15A NCAC 02D .0402 Sulfur Oxides effective September 1, 2011, which were revised to be consistent with the current NAAOS. EPA has made, and will continue to make, these documents generally available electronically through www.regulations.gov and/or in hard copy at the appropriate EPA office (see the ADDRESSES section of this preamble for more information).

# **IV. Final Action**

EPA is approving the aforementioned changes to the North Carolina SIP, because they are consistent with EPA's standards for NO2 and SO2. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective September 18, 2015 without further notice unless the Agency receives adverse comments by August 19, 2015.

If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All adverse comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are

received, the public is advised that this rule will be effective on September 18, 2015 and no further action will be taken on the proposed rule.

Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, the Agency may adopt as final those provisions of the rule that are not the subject of an adverse comment.

# V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. See 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human

health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the Federal Register.

This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 18, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's Federal Register, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

# List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Sulfur dioxide, Reporting and recordkeeping requirements.

Dated: July 6, 2015.

### Heather McTeer Toney,

Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

# PART 52—APPROVAL AND **PROMULGATION OF** IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42. U.S.C. 7401 et seq.

## Subpart II—North Carolina

■ 2. Section 52.1770(c) is amended under Table 1, at Subchapter 2D Air Pollution Control Requirements, Section .0400 Ambient Air Quality Standards by revising the entries for ".0402," and ".0407" to read as follows:

#### § 52.1770 Identification of plan.

(c) \* \* \*

# TABLE 1—EPA APPROVED NORTH CAROLINA REGULATIONS

State citation	Title/subject		citation Title/subject State effective date		State effective date	EPA approval date	Explanation	
		Subchapter 2D A	Air Pollution Contro	I Requirements				
*	*	*	*	*	*	*		
		Section .0400	Ambient Air Qualit	y Standards				
*	*	*	*	*	*			
Sect .0402	Sulfur Dioxide			9/1/2011	7/20/2015 [Insert citation of publication].			
*	*	*	*	*	*	*		
Sect .0407	Nitrogen Dioxid	e		9/1/2011	7/20/2015 [Insert citation of publication].			
*	*	*	*	*	*	*		

[FR Doc. 2015–17683 Filed 7–17–15; 8:45 am]

BILLING CODE 6560-50-P

# **ENVIRONMENTAL PROTECTION AGENCY**

#### 40 CFR Part 261

[EPA-R01-RCRA-2012-0447; FRL-9930-54-Region-1]

**Hazardous Waste Management** System; Identification and Listing of **Hazardous Waste Amendment** 

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; amendment.

**SUMMARY:** The Environmental Protection Agency (EPA) is amending the exclusion for International Business Machines Corporation (IBM) in Essex Junction, Vermont to reflect changes in ownership and name.

DATES: This amendment is effective on July 20, 2015.

#### FOR FURTHER INFORMATION CONTACT:

Sharon Leitch, RCRA Waste Management and UST Section, Office of Site Remediation and Restoration, (Mail Code: OSRR07–01), EPA Region 1, 5
Post Office Square, Suite 100, Boston, MA 02109–3912; telephone number: (617) 918–1647; fax number (617) 918–0647; email address: leitch.sharon@epa.gov.

**SUPPLEMENTARY INFORMATION:** In this document EPA is amending appendix IX to part 261 to reflect a change in the ownership and name of a particular facility. Today's notice documents the transfer of ownership and name change by updating appendix IX to incorporate the change in owner's name for the IBM Corporation, Essex Junction, Vermont facility. The exclusion or "delisting" was granted to IBM on September 13, 2012 (see 77 FR 56558). The EPA has been notified that the transfer of ownership of the Essex Junction facility to GLOBALFOUNDRIES U.S. 2 LLC will occur on July 1, 2015.

GLOBALFOUNDRIES has certified that it plans to comply with all the terms and conditions set forth in the delisting and will not change the characteristics of the wastes subject to the exclusion at the Essex Junction facility. This notice documents the change by updating appendix IX to incorporate a change in name.

In accordance with the delisting approval, IBM has completed the quarterly verification testing requirements set forth in paragraph 3.(A) and has submitted the first set of annual testing results in accordance with paragraph 3.(B). As part of this notice, EPA is clarifying the

requirements for annual reporting found in paragraph 3.(B)(iii) of the delisting approval. The paragraph currently requires that the annual test report include the annual testing data and the annual amount of waste in cubic yards disposed of during the calendar year. However, as a result of the timing of the delisting approval, annual testing occurs during August and September of each year and the reports are submitted to EPA soon thereafter. With this notice EPA is clarifying that the reporting of the annual sludge volumes shall occur separately from the annual testing reports. As a result, the delisting is being modified to include paragraph 3.(B)(iv) to reflect this change. We are also clarifying in paragraph 3.(B)(iii) that the annual testing results shall be submitted to EPA within thirty days after both annual samples have been taken.

The changes to appendix IX of part 261 are effective July 20, 2015. The Hazardous and Solid Waste Amendments of 1984 amended section 3010 of the Resource Conservation and Recovery Act (RCRA) to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. As described above, the facility has certified that it is prepared to comply with the requirements of the exclusion. Therefore, a six-month delay in the effective date is not necessary in this case. This provides the basis for making this amendment effective immediately upon publication under

the Administrative Procedures Act pursuant to 5 United States Code (U.S.C.) 5531(d). The EPA has determined that having a proposed rule and public comment on this change is unnecessary, as it involves only a change in company ownership, and a clarification, with all of the same delisting requirements remaining in effect.

#### List of Subjects in 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

**Authority:** Section 3001(f) RCRA, 42 U.S.C. 6921(f)

Dated: June 29, 2015.

#### H. Curtis Spalding,

Regional Administrator, EPA Region 1.

For the reasons set out in the preamble, 40 CFR part 261 is amended as follows:

### PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 1. The authority citation for part 261 continues to read as follows:

**Authority:** 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

■ 2. Table 1 of Appendix IX to part 261 is amended by removing the "IBM Corporation" entry and adding a new entry "GLOBALFOUNDRIES U.S. 2 LLC" in alphabetical order by facility to read as follows:

Appendix IX to Part 261—Waste Excluded Under §§ 260.20 and 260.22

#### TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility Address Waste description

GLOBALFOUNDRIES U.S. 2 LLC Essex Junction, VT (formerly, "IBM Corporation").

Wastewater Treatment Sludge (Hazardous Waste No. F006) generated at a maximum annual rate of 3,150 cubic yards per calendar year and disposed of in a Subtitle D Landfill which is licensed, permitted, or otherwise authorized by a state to accept the delisted wastewater treatment sludge. GLOBALFOUNDRIES U.S. 2 LLC must implement a testing program that meets the following conditions for the exclusion to be valid: 1. Delisting Levels: (A) All leachable concentrations for the following constituents must not exceed the following levels (mg/L for TCLP): Arsenic—5.0; Barium—100.0; Cadmium—1.0; Chromium—5.0; Lead—5.0; Mercury 0.2; and, Nickel—32.4.

#### TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility Address Waste description

- 2. Waste Handling and Holding: (A) GLOBALFOUNDRIES U.S. 2 LLC must manage as hazardous all WWTP sludge generated until it has completed initial verification testing described in paragraph (3)(A) and valid analyses show that paragraph (1) is satisfied and written approval is received by EPA. (B) Levels of constituents measured in the samples of the WWTP sludge that do not exceed the levels set forth in paragraph (1) for two consecutive quarterly sampling events are non-hazardous. After approval is received from EPA, GLOBALFOUNDRIES U.S. 2 LLC can manage and dispose of the non-hazardous WWTP sludge according to all applicable solid waste regulations. (C) Not withstanding having received the initial approval from EPA, if constituent levels in a later sample exceed any of the Levels set in paragraph (1), from that point forward, GLOBALFOUNDRIES U.S. 2 LLC must treat all the waste covered by this exclusion as hazardous until it is demonstrated that the waste again meets the levels in paragraph (1). GLOBALFOUNDRIES U.S. 2 LLC must manage and dispose of the waste generated under Subtitle C of RCRA from the time that it becomes aware of any exceedance.
- 3. Verification Testing Requirements: GLOBALFOUNDRIES U.S. 2 LLC must perform sample collection and analyses in accordance with the approved Quality Assurance Project Plan dated January 27, 2011. All samples shall be representative composite samples according to appropriate methods. As applicable to the method-defined parameters of concern, analyses requiring the use of SW-846 methods incorporated by reference in 40 CFR 260.11 must be used without substitution. As applicable, the SW-846 methods might include Methods 0010, 0011, 0020, 0023A, 0030, 0031, 0040, 0050, 0051, 0060, 0061, 1010A, 1020B,1110A, 1310B, 1311, 1312, 1320, 1330A, 9010C, 9012B, 9040C, 9045D, 9060A, 9070A (uses EPA Method 1664, Rev. A), 9071B, and 9095B. Methods must meet Performance Based Measurement System Criteria in which the Data Quality Objectives are to demonstrate that samples of the GLOBALFOUNDRIES U.S. 2 LLC sludge are representative for all constituents listed in paragraph (1). To verify that the waste does not exceed the specified delisting concentrations, for one year after the final exclusion is granted GLOBALFOUNDRIES U.S. 2 LLC must perform quarterly analytical testing by sampling and analyzing the WWTP sludge as follows: (A) Quarterly Testing: (i) Collect two representative composite samples of the WWTP sludge at quarterly intervals after EPA grants the final exclusion. The first composite samples must be taken within 30 days after EPA grants the final approval. The second set of samples must be taken at least 30 days after the first set. (ii) Analyze the samples for all constituents listed in paragraph (1). Any waste regarding which a composite sample is taken that exceeds the delisting levels listed in paragraph (1) for the sludge must be disposed as hazardous waste in accordance with the applicable hazardous waste requirements from the time that GLOBALFOUNDRIES U.S. 2 LLC becomes aware of any exceedance. (iii) Within thirty (30) days after taking each quarterly sample, GLOBALFOUNDRIES U.S. 2 LLC will report its analytical test data to EPA. If levels of constituents measured in the samples of the sludge do not exceed the levels set forth in paragraph (1) of this exclusion for two consecutive quarters, and EPA concurs with those findings, GLOBALFOUNDRIES U.S. 2 LLC can manage and dispose the non-hazardous sludge according to all applicable solid waste regulations. (B) Annual Testing: (i) If GLOBALFOUNDRIES U.S. 2 LLC completes the quarterly testing specified in paragraph (3) above and no sample contains a constituent at a level which exceeds the limits set forth in paragraph (1), GLOBALFOUNDRIES U.S. 2 LLC may begin annual testing as follows: GLOBALFOUNDRIES U.S. 2 LLC must test two representative composite samples of the wastewater treatment sludge (following the same protocols as specified for quarterly sampling, above) for all constituents listed in paragraph (1) at least once per calendar year. (ii) The samples for the annual testing taken for the second and subsequent annual testing events shall be taken within the same calendar month as the first annual sample taken. (iii) GLOBALFOUNDRIES U.S. 2 LLC shall submit an annual testing report to EPA with all of its annual test results, within thirty (30) days after taking the two annual samples. (iv) GLOBALFOUNDRIES U.S. 2 LLC shall submit to EPA in January of each year the total amount of waste in cubic yards disposed during the previous calendar year.

#### TABLE 1—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility Address Waste description

- 4. Changes in Operating Conditions: If GLOBALFOUNDRIES U.S. 2 LLC significantly changes the manufacturing or treatment process described in the petition, or the chemicals used in the manufacturing or treatment process, it must notify the EPA in writing and may no longer handle the wastes generated from the new process as non-hazardous unless and until the wastes are shown to meet the delisting levels set in paragraph (1), GLOBALFOUNDRIES U.S. 2 LLC demonstrates that no new hazardous constituents listed in appendix VIII of part 261 have been introduced, and GLOBALFOUNDRIES U.S. 2 LLC has received written approval from EPA to manage the wastes from the new process under this exclusion. While the EPA may provide written approval of certain changes, if there are changes that the EPA determines are highly significant, the EPA may instead require GLOBALFOUNDRIES U.S. 2 LLC to file a new delisting petition.
- 5. Data Submittals and Recordkeeping: GLOBALFOUNDRIES U.S. 2 LLC must submit the information described below. If GLOBALFOUNDRIES U.S. 2 LLC fails to submit the required data within the specified time or maintain the required records on-site for the specified time, EPA, at its discretion, will consider this sufficient basis to reopen the exclusion as described in paragraph (6). GLOBALFOUNDRIES U.S. 2 LLC must: (A) Submit the data obtained through paragraph (3) to the Chief, RCRA Waste Management & UST Section, U.S. EPA Region 1, (OSRR07-1), 5 Post Office Square, Suite 100, Boston, MA 02109-3912, within the time specified. All supporting data can be submitted on CD-ROM or some comparable electronic media; (B) Compile, summarize, and maintain on site for a minimum of five years and make available for inspection records of operating conditions, including monthly and annual volumes of WWTP sludge generated, analytical data, including quality control information and, copies of the notification(s) required in paragraph (7); (C) Submit with all data a signed copy of the certification statement in 40 CFR 260.22(i)(12).
- 6. Reopener Language-(A) If, anytime, after disposal of the delisted waste, GLOBALFOUNDRIES U.S. 2 LLC possesses or is otherwise made aware of any environmental data (including but not limited to leachate data or groundwater monitoring data) or any other relevant data to the delisted waste indicating that any constituent is at a concentration in the leachate higher than the specified delisting concentration, then GLOBALFOUNDRIES U.S. 2 LLC must report such data, in writing, to the Regional Administrator and to the Vermont Agency of Natural Resources Secretary within 10 days of first possessing or being made aware of that data. (B) Based on the information described in paragraph (A) and any other information received from any source, the Regional Administrator will make a preliminary determination as to whether the reported information requires Agency action to protect human health or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment. (C) If the Regional Administrator determines that the reported information does require Agency action, the Regional Administrator will notify GLOBALFOUNDRIES U.S. 2 LLC in writing of the actions the Regional Administrator believes are necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing GLOBALFOUNDRIES U.S. 2 LLC with an opportunity to present information as to why the proposed Agency action is not necessary or to suggest an alternative action. GLOBALFOUNDRIES U.S. 2 LLC shall have 30 days from the date of the Regional Administrator's notice to present the information. (D) If after 30 days GLOBALFOUNDRIES U.S. 2 LLC presents no further information or after a review of any submitted information, the Regional Administrator will issue a final written determination describing the Agency actions that are necessary to protect human health or the environment. Any required action described in the Regional Administrator's determination shall become effective immediately, unless the Regional Administrator provides otherwise.
- 7. Notification Requirements: GLOBALFOUNDRIES U.S. 2 LLC must do the following before transporting the delisted waste: (A) Provide a one-time written notification to any state Regulatory Agency to which or through which it will transport the delisted waste described above for disposal, 60 days before beginning such activities; (B) Update the one-time written notification if it ships the delisted waste to a different disposal facility. Failure to provide this notification will result in a violation of the delisting petition and a possible revocation of the decision.

\* \* \* \* \* \* \*

### ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 720, 721, 723, and 725 [EPA-HQ-OPPT-2013-0385; FRL-9927-79] RIN 2070-AJ98

#### TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting

**AGENCY:** Environmental Protection

Agency (EPA).

**ACTION:** Direct Final Rule.

**SUMMARY:** EPA is taking direct final action to amend the Toxic Substances Control Act (TSCA) section 5 electronic reporting regulations. These electronic reporting regulations establish standards and requirements for use of EPA's Central Data Exchange (CDX) to electronically submit premanufacture notices (PMNs), other TSCA section 5 notices, and support documents to the Agency. This rule provides the user community with new methods for accessing the e-PMN software, new procedures for completing the electronic-PMN (e-PMN) form, changes to the CDX registration process, adds the requirement to submit "bona fide intents to manufacture" electronically, and changes to the procedure for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA. This action is intended to further streamline and reduce the administrative costs and burdens of TSCA section 5 notifications for both industry and EPA.

DATES: This direct final rule is effective January 19, 2016 without further notice, unless EPA receives adverse comment on or before August 19, 2015. If EPA receives adverse comments on this action, EPA will withdraw the rule before its effective date. EPA will then issue a proposed rule, providing a 30-day period for public comment.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2013-0385, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Greg Schweer, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; MC 7405M; telephone number: (202) 564–8469; email address: Schweer.greg@ena.gov

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: TSCA-Hotline@epa.gov.

#### SUPPLEMENTARY INFORMATION:

#### I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you manufacture (which includes import) or process chemicals for commercial purposes that are subject to TSCA. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide for readers regarding industries within which entities are likely to be affected by this action. Potentially affected entities may include, but are not limited to:

 Manufacturers and processors of chemical substances or mixtures (NAICS codes 325 and 32411).

Full descriptions of these NAICS codes and related establishments are maintained by the U.S. Census Bureau online at https://www.census.gov/eos/ www/naics/index.html. Other types of entities not listed in this unit could also be affected. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in 40 CFR parts 700, 720, 721, 723, and 725 for TSCA section 5-related obligations. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under FOR FURTHER INFORMATION CONTACT.

B. What is the agency's authority for taking this action?

TSCA gives EPA broad authority to regulate the manufacture (including

import) and processing of chemical substances. It is the expressed intent of Congress that EPA carry out TSCA in a reasonable and prudent manner, and in consideration of the impacts that any action taken under TSCA may have on the environment, the economy, and society (TSCA section 2). The underlying requirements promulgated under this broad authority and amended by this final rule require manufacturers (including importers) and processors of chemical substances and mixtures to:

• Notify EPA at least 90 days before manufacturing a new chemical substance for commercial purposes (TSCA section 5(a)(1)(A)).

• Notify EPA at least 90 days before manufacturing or processing the chemical substance for any use of a chemical substance that EPA has determined to be a "significant new use" (TSCA section 5(a)(1)(B)).

Section 5(h)(4) of TSCA authorizes EPA, upon application and by rule, to exempt the manufacturer of any new chemical substance from part or all of the provisions of TSCA section 5.

In addition, the Paperwork Reduction Act (PRA) requires Federal agencies to manage information resources to reduce information collection burdens on the public; increase program efficiency and effectiveness; and improve the integrity, quality, and utility of information to all users within and outside an agency, including capabilities for ensuring dissemination of public information, public access to Federal Government information, and protections for privacy and security (44 U.S.C. 3501 et seq.).

Finally, the Government Paperwork Elimination Act (GPEA) (Pub. L. 105–277 (44 U.S.C. 3504)) instructs Federal agencies to use and accept from the public, when practicable, electronic forms, electronic filings, and electronic signatures in the conduct of official business with the public.

C. What action is the agency taking?

This direct final rule amends the TSCA Section 5 Premanufacture and Significant New Use Notification regulations at 40 CFR parts 720, 721, 723 and 725, by mandating the use of an updated version of the e-PMN reporting software. In the Federal Register of January 2010 (75 FR 773) (FRL-8794-5), EPA issued a final rule requiring the use of the e-PMN reporting software for the submission of PMNs and other TSCA section 5 notices and support documents to the Agency using the Internet through CDX. This new version of the e-PMN software will operate as a "cloud" software system ("Thin Client Version") rather than as a downloadable software system ("Thick

Client Version"). In addition, the direct final rule extends electronic reporting requirements to notices of "bona fide intent to manufacture" (bona fides); corrects certain regulatory cross-references in 40 CFR parts 720 and 721; standardizes the use of "manufacture" and similar language in 40 CFR parts 720, 721, and 725; and specifies electronic reporting procedures for the notification of new manufacturing sites pursuant to 40 CFR 723.50(j)(6)(ii).

#### D. Why is the agency taking this action?

The Agency is taking this action to further facilitate electronic reporting under TSCA and to streamline and reduce the administrative costs and burdens of TSCA section 5 notifications for both industry and EPA. This change will eliminate certain firewall and file submission size limitations that exist with the current version of the software. This change will also enable submitters to work directly online within the Thin Client Version which provides a more efficient way of accessing the e-PMN software and transmitting data to EPA. In addition, the extension of the electronic reporting requirements ensures that submitters are able to use a single method of submission for related TSCA section 5 notifications.

#### E. What are the impacts of this action?

EPA believes that both the transition from the Thick Client Version to the Thin Client Version of the e-PMN software, as well as the changes to the procedures for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50, will streamline and reduce slightly the administrative costs and burdens associated with TSCA section 5 notifications for both industry and EPA; the only burden expected is the time it takes a submitter to familiarize themselves with the rule. EPA believes that submitters of bona fide intents to manufacture will experience burden and cost savings because the time required to enter, review, and edit their notices using the e-PMN software and transmit their submissions to EPA electronically will be less than that for the existing paper-based process. See also the discussion in Unit IV.

#### II. Direct Final Rule Procedures

#### A. Why is EPA using a direct final rule?

EPA is publishing this rule without a prior proposed rule because the Agency views this as a noncontroversial action and anticipates no adverse comment. As addressed in Unit I.A., this action requires the use of a new version of the

e-PMN software that is easier to access, features enhanced submission security. and eliminates size limitations on the submitted files. The action also corrects certain outdated regulatory crossreferences, and standardizes terminology across certain regulatory provisions. If EPA receives adverse comment, the agency will publish a timely withdrawal in the Federal Register informing the public that the rule will not take effect. If EPA does not receive any timely adverse comment, this amendment will become effective as indicated under DATES without any further action by EPA.

### B. What should I consider as I prepare my comments for EPA?

- 1. Submitting CBI. Do not submit this information to EPA through http:// www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.
- 2. Tips for preparing your comments. When preparing and submitting any comments, see the commenting tips at http://www.epa.gov/dockets/comments.html.

#### III. Overview of the CDX, CISS, and the Thin Client Version of the e-PMN Software

#### A. What is CDX?

CDX is EPA's electronic system for environmental data exchange to the Agency. CDX also provides the capability for submitters to access their data through the use of web services. CDX enables EPA to work with stakeholders, including governments, regulated industries, and the public, to enable streamlined, electronic submission of data via the Internet. For more information about CDX, go to http://epa.gov/cdx. TSCA section 5 submissions will be prepared and submitted through Chemical Information Submission System (CISS) in CDX.

#### B. What is CISS?

CISS is a web-based reporting tool developed by EPA for use in submitting data, reports, and other information under certain sections of TSCA electronically to the Agency. CISS provides user-friendly navigation, works with CDX to secure online communication, creates a completed Portable Document Format (PDF) for review prior to submission, and enables data, reports, and other information to be submitted easily as PDF attachments, or by other electronic standards, such as XML.

### C. What is the thin client version of the e-PMN software?

The thin client version of the e-PMN software is a submission module within CISS. Following promulgation of the e-PMN final rule in 2010, EPA launched submission modules in CISS for TSCA Chemical Data Reporting, TSCA section 4 test data submissions, TSCA section 8(a) preliminary assessment information rules, TSCA section 8(d) health and safety data reporting rules, and mandatory notifications of substantial risk under TSCA section 8(e) along with related, voluntary "For Your Information" submissions. EPA has enhanced the e-PMN software in the thin client version to incorporate several functions already available to submitters in the other CISS submission modules, including:

1. Enhanced CDX Registration and Submission Process. When submitters complete new CDX registration activities, they are prompted to choose 5 out of 20 offered questions and provide answers to each of those 5 questions. In order to electronically sign and submit data to the EPA or to download the Copy of Record in CDX, a user must correctly answer 1 randomly selected question of the 5 questions chosen by that user (i.e., a "20-5-1" security question) before the transaction can be completed. When the 20-5-1 security question is answered correctly, the thin client version of the software then encrypts the information and transaction is completed.

2. Optional online Electronic
Signature Agreement (ESA) and identity validation. The thin client version of the e-PMN software enables electronic submitters who are newly applying for the Authorized Official (AO) role in CDX to validate their personal identities electronically via LexisNexis. Those submitters applying for the AO role who choose to not use LexisNexis, or for whom LexisNexis could not validate their identities, will need to follow the current, paper-based e-PMN identity

validation process. In CDX, these submitters will instead select the "Sign Paper Form" option. CDX will then instruct the user to print, sign, and mail the ESA (ESA processing by EPA may take up to 10 business days from the date of receipt). Since support persons are not able to sign and complete submissions or download the Copy of Record for a submission, they will be able to register with CDX without authentication of identity.

3. AO Role Expansion. The role of the AO has been expanded. Not only does the AO of the submitting company certify initial notices and submit all types of section 5 documents to EPA via CDX, the role has been broadened to allow non-certifying AOs (e.g., technical contacts, consultants etc.) to conduct all TSCA section 5 business on behalf of the company except for certifying and submitting initial notices including joint submissions and letters of support. The role for the registered support person has also changed. Support persons will have the ability only to edit information in forms to which they have been granted access by the AO.

4. Updated user roles/designations. For joint submissions and/or letters of support, there are new designations/ roles assigned in registration referred to as "secondary" (for both AOs and support persons). The "primary" role designation is for persons who will create and submit the main PMN and supporting documents. The "secondary" role designation is for persons who will create and submit joint submissions and letters of support.

### D. What are the benefits of the thin client version of the e-PMN software?

EPA developed the Thin Client Version of the e-PMN software to provide a more efficient way of accessing the e-PMN software and completing the e-PMN form. The Thin Client Version of the software was also designed to enable more efficient data transmittal, including increasing the size of files that can be submitted to EPA. By moving from the Thick Client Version of the e-PMN software to the Thin Client Version, the Agency has eliminated the roadblocks associated with firewalls that were encountered by some users of the Thick Client Version by allowing submitters to work directly online within the Thin Client Version or, if they choose, to work offline using an XML schema which allows them to later upload their information to the Thin Client Version. When preparing and completing submissions in the thin client version, submitters will find that sharing files within the software makes the information readily accessible to

registrants of the submitting company and their designated support persons. Also, once a user completes the relevant data fields and attaches appropriate PDF files or other allowable file types, the web-based tool validates the submission by performing a basic error check and makes sure all the required fields and attachments are provided and complete. Finally, the Thin Client Version assures that submitters will always use the most up-to-date version of the e-PMN software when initiating, updating, and/ or completing their submissions in CISS.

In addition, the thin client version improves EPA data management by altering the process for submitting amendments to a valid notice. Currently, submitters would electronically submit only the amended sections of the form. Under the new procedure, companies will revise the necessary information in the initial notice or a previously modified version of the notice and an entire updated notice will then be resubmitted to EPA. This provides EPA with a complete, updated version of the entire submission in one document.

# E. Will CBI be protected when using the thin client version of the e-PMN software?

Yes. The application has been designed to support TSCA CBI needs by providing a secure environment that meets Federal standards. The application uses Transportation Layer Security with 256-bit digital encryption, and the data is encrypted at rest using a key that only a user knows. All data remains encrypted until it is behind several EPA firewalls and within the EPA CBI LAN, and all encryption algorithms are compliant with Federal Information Processing Standards. In addition, users must have valid CDX credentials (user name and password combination) to access the application, and they choose and provide answers to 5 of the 20 offered questions in CDX. In order to access the CDX account and submit data to the EPA or to download the Copy of Record, a user must correctly answer one of the 5 chosen questions associated with the CDX account.

#### F. How do I submit TSCA section 5 notifications and support documents using CDX and the "Thin Client Version" of the e-PMN software?

EPA has prepared a comprehensive user guide for CISS users that addresses CDX registration and electronic signatures, general submission preparation and completion, and submission status tracking notifications (Ref. 1). This user guide is available through EPA's Web page at http://www.epa.gov/oppt/chemtest/ereporting. EPA has also prepared a separate user guide for the e-PMN software module in CISS (i.e., the Thin Client Version) (Ref. 2) which is available through EPA's Web page at http://epa.gov/oppt/newchems/epmn/epmn-index.htm.

### IV. Description of Changes to Required Reporting Procedures

A. What are the new requirements for "Bona Fide Intents to Manufacture"?

This direct final rule extends the electronic reporting requirement to submit PMNs, other TSCA section 5 notices, and support documents to the Agency electronically to include the submissions of bona fides. A person who intends to manufacture a chemical substance not listed by specific chemical name in the public portion of the Inventory of Chemical Substances may ask EPA, through submission of a bona fide intent to manufacture. whether the substance is included in the confidential portion of the Inventory and, thus, be able to determine whether submission of a Premanufacture Notice or Significant New use Notice in accordance with TSCA section 5(a)(1) is required. Bona fides were not included within the scope of the January 2010 final rule due to the variability and frequency of these types of submissions. However, in that rule, EPA stated that this and other types of submissions could be considered for electronic reporting in the future. Bona fides are currently submitted in paper form only according to the requirements of 40 CFR 720.25, 721.11 and 725.15 which do not prescribe a format, only required content. This direct final rule requires that submitter to submit this information electronically using the Thin Client Version of the e-PMN software

B. What are the new requirements for notification of new manufacturing sites?

As required under 40 CFR 723.50(j)(6)(ii), a manufacturer (including importer) must notify EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50. Under the existing regulation, companies may use, but are not required to use, the Notice of Commencement (NOC) to report manufacturing site changes to EPA. Under the existing regulation, however, if the NOC form is used for this purpose, the manufacturer must add a statement to the NOC form that the notification is an amendment to the original

exemption. The electronic version of the NOC in the e-PMN software has been designed to solely deal with NOCs and will not accommodate notifications of manufacturing site changes. Therefore, this direct final rule requires that such notifications of changes in manufacturing sites be submitted electronically to EPA via CDX as a "support document" to the original notification.

### C. How has the required method of submission changed?

EPA's electronic reporting program has evolved significantly following the promulgation of the e-PMN final rule in 2010. Following promulgation of that rule, EPA announced web-based electronic reporting workflows for TSCA Chemical Data Reporting, TSCA section 4 test data submissions, TSCA section 8(a) preliminary assessment information rules, TSCA section 8(d) health and safety data reporting rules, and mandatory notifications of substantial risk under TSCA section 8(e) along with related, voluntary "For Your Information" submissions.

Under the current e-PMN rule requirements, TSCA section 5 submitters already must register in CDX and complete an electronic signature agreement before submitting any information to EPA electronically via CDX using the e-PMN software. This direct final rule requires all persons who will be working online on a submission to register with EPA's CDX and to use the e-PMN module within CISS to prepare data for submission. EPA expects that most TSCA section 5 submitters are already registered in CDX. Those users do not need to reregister with CDX, nor will they need to re-verify their identities. In order to use the Thin Client Version of the e-PMN software required under this direct final rule, users who have previously registered with CDX under the TSCA workflow to submit TSCA section 5 submissions, or other CDX workflows such as the Toxics Release Inventory TRI-ME web reporting, will only need to add the "Submission for Chemical Safety and Pesticide Program (CSPP)" CDX workflow to their user profiles.

### D. Will EPA offer any exceptions to the transition to the thin client version?

No. The Agency has concluded that the overall benefits from everyone using the more efficient Thin Client Version of the e-PMN software and submission through CDX exceed those associated with maintaining a multi-optioned reporting approach (Ref. 3). The Agency recognizes that there is the potential for costs and burden associated with

unpredictable or unanticipated technical difficulties in electronic filing or with the conversion to the "Thin Client Version." However, EPA expects that the transition costs and any transition difficulties will be mitigated by:

- 1. EPA's planned outreach and training sessions prior to the effective date of this direct final rule. EPA believes that the six-month phase-out period for the Thick Client Version between the date of publication and the effective date of this direct final rule provides submitters with ample time to register to use and become proficient with the Thin Client Version of the e-PMN software. EPA will accept submissions using the Thin Client Version of the e-PMN software beginning on September 3, 2015. After January 19, 2016, use of the Thin Client Version of the e-PMN software becomes mandatory.
- 2. EPA's offering of an XML schema to those submitters who choose to work on their submissions offline rather than online, which allows them to later upload their information to the Thin Client Version of the e-PMN software for submission using CDX. The six-month phase-out period for the period between the date of publication and the effective date of the final rule should provide these users adequate time to implement the XML schema on their systems.
- 3. EPA's technical support following the effective date of this final rule.

# E. Will all types of TSCA section 5 notices and communications be submitted via e-PMN software?

At this time, the Agency lacks electronic reporting capability for some TSCA section 5-related notices (e.g., polymer exemption annual reports); certain support documents (i.e., TSCA section 5(e) consent orders or orders imposed pursuant to TSCA section 5(e)(2)(B)); and certain communications (e.g., pre-notice communications and TSCA Inventory correspondence), due to the variability and infrequent nature of these types of submissions. EPA may consider offering electronic reporting of these and other submissions in the future.

### V. Corrections to 40 CFR Parts 720, 721, 723 and 725

The direct final rule also corrects certain regulatory cross-references in 40 CFR parts 720 and 721 and standardizes the use of "manufacture" and similar language in 40 CFR parts 720, 721, and 725.

1. Minor change to definition of "article" in 40 CFR 720.3. The current definition of "article" at 40 CFR 720.3(c)

- incorrectly references 40 CFR 720.36(g)(5) concerning changes in chemical composition which have no commercial purpose separate from that of the article. This rulemaking corrects the cross-reference to 40 CFR 720.30(h)(5).
- 2. Removal of the cross-reference to 40 CFR 710.7(e)(2)(v) in 40 CFR 720.25(b)(4) and 40 CFR 721.11(d). The CFR at  $\S$  720.25(b)(4) and  $\S$  721.11(d) currently cross-references both 40 CFR 710.7(e)(2)(v) and 40 CFR 720.85(b)(3)(iii). These cross-references should only be to 40 CFR 720.85(b)(3)(iii); 40 CFR 710.7(e)(2)(v) no longer exists.
- 3. Use of "manufacture or import" and similar language in 40 CFR 720.25(b), 40 CFR 721.11 and 40 CFR 725.15. The definition of "manufacture" in section 3(7) of TSCA includes both manufacture and import. However, in many places in TSCA section 5 regulations in parts 720, 721, 725 and elsewhere the terms "manufacture or import" or "manufacture, import or process" are used. EPA is revising "manufacture" and "manufacture" in some of the provisions affected by this rule to clarify that import is included in manufacture under TSCA. This is not intended to make any substantive change to the regulations. As EPA amends other TSCA regulations with similar language in the future, the Agency intends to make corresponding changes.
- 4. Removal of the definition of "optical disc" in 40 CFR 720.3. The January 2010 (75 FR773) final rule phased out the electronic submission of TSCA section 5 notices to EPA via optical disc as a valid method of submission as of April 6, 2012. Therefore, the definition currently presented at 40 CFR 720.3(kk) is obsolete and will be removed.
- 5. Use of CDX to submit written requests for suspension of the notice review period in 40 CFR 720.75. The January 2010 final rule phased out paper submissions of TSCA section 5 notices to EPA as of April 6, 2011, and the electronic submission of TSCA section 5 notices to EPA via optical disc as a valid method of submission as of April 6, 2012. However, 40 CFR 720.75(b)(4) continues to provide that written requests for suspension of the notice review period may be submitted to EPA on paper, on optical disc, or in CDX. This final rule corrects 40 CFR 720.75 to specify that written suspension requests must be submitted to EPA via CDX.

#### VI. Estimated Economic Impact

The Agency's estimated economic impact of this direct final rule is presented in a document entitled "Economic Analysis of the TSCA Section 5 Premanufacture and Significant New Use Notification Electronic Reporting; Revisions to Notification Regulations" (Economic Analysis) (Ref. 3), a copy of which is available in the docket and is briefly summarized in this unit. In the economic analysis supporting the January 6, 2010 (75 FR 773) e-PMN final rule, EPA estimated that the electronic submission of TSCA section 5 notices and support documents would reduce the burden and cost associated with the paper-based reporting process of TSCA section 5 notices and support documents (Ref. 4). This direct final rule amends the existing premanufacture notification regulation to mandate the use of the Thin Client Version of the e-PMN reporting software, require use of electronic reporting of TSCA section 5 bona fides, and amends the procedures for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50. These amendments are expected to further streamline and reduce the administrative costs and burdens associated with TSCA section 5 notifications for both industry and EPA.

The Thin Client Version of the e-PMN software will reside as a module within CISS in CDX. The Thin Client Version will eliminate certain firewall and file submission size limitations, as well as reduce the potential for invalid submissions through built-in validation procedures. Use of the Thin Client Version also assures that should revisions be made by EPA, submitters will always use the most up-to-date version of the e-PMN software when initiating, updating, and/or completing their submission in CISS.

Making the software available to industry is expected to result in cost savings for both industry and EPA. However, this direct final rule, which includes a new requirement for electronic submission of bona fide notices and changes to the procedures for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50, may result in some temporary increase in cost to some industry users as they make the transition to the new method of submission. As a result of making the software available, EPA believes that submitters of bona fide notices will experience burden and cost savings

because the time required to enter, review, and edit their notices using the e-PMN software and transmit their submissions to EPA electronically will be less than that for the existing paperbased process. In EPA's economic analysis (Ref. 3), estimated burden and cost savings are presented in comparison to the burden and costs that will be incurred if industry were to continue submitting notices via paper, as was outlined in the previous Information Collection Request (ICR) (Ref. 5). OMB has already approved the underlying information collection requirements described in this direct final rule under OMB control numbers 2070-0012 and 2070-0038 (EPA Information Collection Request (ICR) No. 0574.15, Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances (Ref. 5) and EPA ICR No. 1188.11, TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals (Ref. 6)), respectively. EPA has submitted requests for additional approval to OMB under PRA (Refs. 8 and 9) because the direct final rule alters the required form and format of the existing, approved collections of information.

Once the rule is fully implemented, EPA estimates a net burden savings to industry of 180 hours and a net cost of approximately \$4,000 in the first year. In subsequent years, EPA estimates an annual net burden savings to industry of 489 hours and annual net cost savings of approximately \$17,000. The Agency is projected to experience an annual net burden savings of 40 hours and annual net cost savings of \$3,000 for these same submissions once the rule is fully implemented.

Requiring use of the e-PMN software for submission of bona fides (40 CFR 720.25, 40 CFR 721.11 and 40 CFR 725.15), suspension requests (40 CFR 720.75), and changes in manufacturing sites (40 CFR 723.50(j)(6)) eliminates the option of submitting paper. To the extent that any firms would otherwise submit these notices on paper, these firms may incur some costs in order to meet these mandatory submission requirements. For example, some industry users may incur costs related to adjustments to internal processes or recordkeeping systems, and investments in compatible information technology. At this time, EPA is unable to estimate what these costs might be. However, firms have generally been required to file section 5 notifications electronically using the e-PMN software since April 2012, and a final rule published in the Federal Register of December 4, 2013(78 FR 72818) (FRL–9394–6) requires that any new NOCs for PMNs filed in paper prior to April 2012 be submitted electronically using the e-PMN software (Ref. 7). Firms expected to submit bona fides, suspension requests, and changes in manufacturing sites are believed by EPA to primarily be the same firms that are already complying with the existing regulations. EPA therefore does not believe that many, if any, firms would incur such costs only for the electronic submission of bona fides or notifications of manufacturing site changes for a previously submitted PMN.

The total annual burden to society (industry plus EPA) from the e-PMN software is expected to decrease by 57 hours in the first year and 529 hours in subsequent years. The total cost to society is expected to increase by \$1,000 in year one and decrease by \$20,000 in future years. These cost savings may be diminished by any transactions costs that firms compelled to switch to the new software system might face for submission of bona fides. EPA believes that both the transition from the Thick Client Version to the Thin Client Version, as well as the changes to the procedures for notifying EPA of any new manufacturing site of a chemical substance for which an exemption was granted by EPA under 40 CFR 723.50, will have a negligible impact on industry or Agency burden or costs, and, therefore, the cost savings

### Analysis (Ref. 3). VII. References

The public docket for this final rule has been established. The following is a listing of the documents referenced in this preamble that have been placed in the public docket for this final rule under docket ID number EPA–HQ–OPPT–2013–0385, which is available for inspection as specified under ADDRESSES.

associated with these changes are only

described qualitatively in the Economic

- 1. EPA. Central Data Exchange CSPP CDX Registration Guide, December 12, 2011.
- 2. EPA. Section 5 Notices and Supports Users Guide. December 20, 2013 (available at: http://www.epa.gov/oppt/newchems/epmn/epmn-index.htm).
- 3. EPA. Economic and Policy Analysis
  Branch, Office of Pollution Prevention
  and Toxics (OPPT). Economic Analysis
  of the TSCA Section 5 Premanufacture
  and Significant New Use Notification
  Electronic Reporting; Revision to
  Notification Regulations. November 17,
  2014.
- 4. EPA. Economic and Policy Analysis Branch, Office of Pollution Prevention and Toxics (OPPT). Economic Analysis of the Amendments to TSCA Section 5 Premanufacture and Significant New Use

- Notification Requirements Final Rule. July 13, 2009.
- 5. EPA Information Collection Request (ICR) No. 0574.15, Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances.
- EPA ÎCR No. 1188.12, TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals.
- EPA. Electronic Reporting Under the Toxic Substances Control Act; Final Rule.
   Federal Register (78 FR 72818, December 4, 2013) (FRL-9394-6).
- 8. EPA. Supporting Statement for a Request for OMB Review under The Paperwork Reduction Act. Revision to Premanufacture Review Reporting and Exemption Requirements for New Chemical Substances and Significant New Use Reporting Requirements for Chemical Substances (Direct Final Rule; RIN 2070–AJ98). EPA ICR No. 0574.16. OMB Control Number 2070–0012.
- EPA. Supporting Statement for a Request for OMB Review under The Paperwork Reduction Act. Request for a Non-Substantive Change to an Existing Approved Information Collection, TSCA Section 5(a)(2) Significant New Use rules for Existing Chemicals. EPA ICR No. 1188.12; OMB Control Number 2070– 0038.

### VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action as defined by Executive Order 12866 (58 FR 51735, October 4, 1993). Accordingly, this action was not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). EPA has prepared an Economic Analysis for this action (Ref. 3), which is available in the docket for this final rule and is summarized in Unit VI.

#### B. Paperwork Reduction Act

The information collection activities in this direct final rule been submitted for approval to OMB under the PRA (44 U.S.C. 3501 et seq.) pursuant to the procedures at 5 CFR 1320.5(c)(1) and 1320.10(a). The underlying requirements are approved under OMB control numbers 2070–0012 and 2070–0038. However, EPA has submitted requests for additional approval to OMB under PRA because the direct final rule alters the required form and format of the existing, approved collections of information.

The Information Collection Request (ICR) document that EPA prepared to

address the direct final rule requirements related to EPA's New Chemicals Program has been assigned EPA ICR number 0574.16 (Ref. 8). This ICR addresses the required use of the Thin Client version of the e-PMN software system in CDX to complete their TSCA section 5 submissions to EPA's New Chemicals Program instead of a downloadable Thick Client version of the e-PMN software system. In addition, this ICR addresses the mandatory electronic submission of bona fide notices and notifications of new manufacturing sites of chemical substances for which an exemption was granted by EPA under 723.50.

As addressed in EPA ICR No. 0574.16, the total burden to industry is expected to decrease 182 hours and the total cost is expected to increase by \$3,988 in the first year of the rule, for a total burden of 2,312 hours and \$155,699. This includes an average per firm burden of 0.82 hours for rule familiarization for 336 TSCA section 5 submitters, a persubmission burden of 17.0 hours for electronic reporting of 116 bona fide submissions, a per-registrant burden 0.43 hours for 93 new technical labor CDX registrations, and a-per registrant burden of 1.07 hours for 23 new managerial CDX registrants. In all subsequent years of the rule the total industry burden is expected to decrease by 485 hours and \$17,199. This includes a per submission burden of 17.0 hours for electronic reporting of 116 bona fide submissions, a per-registrant burden 0.43 hours for 46 new technical labor CDX registrations, and a per-registrant 1.07 hours for 12 new managerial CDX registrants.

Ĭn addition, EPA has been assigned EPA ICR number 1188.12 (Ref. 9) to the ICR document that addresses the direct final rule requirements related EPA's Existing Chemicals Program (i.e., the required use of the Thin Client version of the e-PMN software system in CDX to complete their TSCA section 5 submissions to EPA's Existing Chemicals Program instead of a downloadable Thick Client version of the e-PMN software system). The direct final rule would only require firms who must already submit significant new use notices for existing chemicals to use the new electronic reporting tool. EPA, therefore, did not estimate any rulerelated burden changes for this ICR.

You can find a copy of these ICR documents in the docket for this direct final rule. Any comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden must be to the EPA using the docket

identified at the beginning of this direct final rule by August 19, 2015. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oria\_submissions@omb.eop.gov*, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than August 19, 2015.

Responses to the collection of information are mandatory, pursuant to EPA's authority under TSCA and PRA (as described in Unit I.C.). However, the changes to the information collection requirements in this direct final rule are not enforceable until OMB approves them. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

#### C. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C § 601 et seq. In making this determination, the impact of concern is any significant adverse economic impact on small entities, because the primary purpose of a final regulatory flexibility analysis is to identify and address regulatory alternatives that "minimize the significant economic impact on small entities" 5 U.S.C. 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule has no net burden effect on the small entities subject to the rule.

As indicated previously, this final rule is expected to reduce the existing regulatory burden. The factual basis for the Agency's certification under the RFA is presented in the small entity impact analysis prepared as part of the Economic Analysis for this final rule (Ref. 3), and is briefly summarized in Unit IV.

D. Unfunded Mandates Reform Act and Executive Orders 13132 and 13175

This action will not have substantial direct effects on State, local, or tribal governments, on the relationship between the Federal Government and States or Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and States or Indian Tribes. As a result, no action is required under Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), or under Executive Order 13175,

entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000). Nor does it impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531–1538).

E. Executive Orders 13045, 13211, and 12898

As indicated previously, this action is not a "significant regulatory action" as defined by Executive Order 12866. As a result, this action is not subject to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) and Executive Order 13211 entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). In addition, this action also does not require any special considerations under Executive Order 12898 entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations' (59 FR 7629, February 16, 1994).

F. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

#### IX. Congressional Review Act

Pursuant to the CRA, 5 U.S.C. 801 *et seq.*, EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

### List of Subjects in 40 CFR Parts 720, 721, 723, and 725

Environmental protection, Chemicals, Electronic reporting, Hazardous substances, Reporting and recordkeeping requirements.

Dated: July 10, 2015.

#### Louise P. Wise,

Acting Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, 40 CFR chapter I is amended as follows:

#### PART 720—[AMENDED]

■ 1. The authority citation for part 720 continues to read as follows:

Authority: 15 U.S.C 2604, 2607, and 2613.

- 2. In § 720.3:
- a. Revise paragraph (c).
- b. Remove paragraph (kk).

- c. Redesignate paragraph (ll) as (kk).d. Revise newly redesignated
- paragraph (kk).
  The revisions read as follows:

#### § 720.3 Definitions.

\* \* \* \* \*

(c) *Article* means a manufactured item:

(1) Which is formed to a specific shape or design during manufacture;

(2) Which has end use function(s) dependent in whole or in part upon its shape or design during end use; and

- (3) Which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 720.30(h)(5), except that fluids and particles are not considered articles regardless of shape or design.
- (kk) Support documents means material and information submitted to EPA in support of a TSCA section 5 notice, including but not limited to, correspondence, amendments (if notices for these amendments were submitted prior to January 19, 2016), and test data. The term "support documents" does not include orders under TSCA section 5(e) (either consent orders or orders imposed pursuant to TSCA section 5(e)(2)(B)).
- 3. In § 720.25, revise paragraphs (b)(1), (b)(2) introductory text, (b)(2)(i) and (ii), and (b)(4), (5), (6), and (7) to read as follows:

### § 720.25 Determining whether a chemical substance is on the Inventory.

(1) A chemical substance is listed in the public portion of the Inventory by a specific chemical name (either a Chemical Abstracts (CA) Index Name or a CA Preferred Name) and a Chemical Abstracts Service (CAS) Registry Number if its identity is not confidential. If its identity is confidential, it is listed in the public portion of the Inventory by a TSCA Accession Number and a generic chemical name that masks the specific substance identity. The confidential substance is listed by its specific chemical name only in the confidential portion of the Inventory, which is not available to the public. A person who intends to manufacture (including import) a chemical substance not listed by specific chemical name in the public portion of the Inventory may ask EPA whether the substance is included in the confidential Inventory. EPA will answer such an inquiry only if EPA determines that the person has a bona fide intent to

manufacture (including import) the chemical substance for commercial purposes.

- (2) To establish a bona fide intent to manufacture (including import) a chemical substance, the person who proposes to manufacture the substance must submit the request to EPA via CDX. Prior to submission to EPA via CDX, such bona fide intents to manufacture (including import) must be generated and completed using e-PMN software. See § 720.40(a)(2)(ii) for information on how to access the e-PMN software. A bona fide intent to manufacture (including import) must contain:
- (i) Except as provided in paragraphs (b)(3)(i) and (ii) of this section, the specific chemical identity of the substance that the person intends to manufacture (including import), using the currently correct CA Index name for the substance and the other correct chemical identity information in accordance with § 720.45(a) (1), (2), and (3).
- (ii) A signed statement that the person intends to manufacture (including import) that chemical substance for commercial purposes.
- (4) EPA will review the information submitted by the proposed manufacturer (including importer) under this paragraph to determine whether it has a *bona fide* intent to manufacture (including import) the chemical substance. If necessary, EPA will compare this information to the information requested for the confidential chemical substance under § 720.85(b)(3)(iii).
- (5) If the proposed manufacturer (including importer) has shown a bona fide intent to manufacture (including import) the substance, and has provided sufficient unambiguous chemical identity information so EPA can make a conclusive determination of the chemical substance's Inventory status, EPA will search the confidential Inventory and inform the proposed manufacturer (including importer) whether the chemical substance is on the confidential Inventory.
- (6) If the chemical substance is found on the confidential Inventory, EPA will notify the person(s) who originally reported the chemical substance that another person has demonstrated a *bona fide* intent to manufacture (including import) the substance and therefore was told that the chemical substance is on the Inventory.
- (7) A disclosure of a confidential chemical identity to a person with a bona fide intent to manufacture

(including import) the particular chemical substance will not be considered a public disclosure of confidential business information under section 14 of the Act.

\* \* \* \* \*

■ 4. In § 720.40, revise paragraphs (a)(2)(i), (a)(2)(ii) introductory text, and (e)(1) and (3) to read as follows:

#### § 720.40 General.

- (a) \* \* \* (2) \* \* \*
- (i) Submission via CDX. TSCA section 5 notices and any related support documents must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, such notices must be generated and completed on EPA Form 7710–25 using e-PMN software.
- (ii) You can access the e-PMN software as follows:

\* \* \* \*

(e) Agency or joint submissions—(1) A manufacturer (including importer) may designate an agent to assist in submitting the notice. If so, only the manufacturer (including importer), and not the agent, signs the certification on the form.

(2) \* \* \*

- (3) Only the Authorized Official (AO) of a submitting company can certify initial notices and submit all TSCA section 5 documents.
- (i) An AO can authorize other persons to be non-certifying AOs who may conduct all section 5 business on behalf of the submitting company except for certifying and submitting initial notices to EPA via CDX.
- (ii) An AO may grant access to a support registrant to edit section 5 documents.

\* \* \* \*

- 5. In § 720.75:
- a. Revise paragraph (b)(2).
- b. Remove paragraphs (b)(3) and (4).
- c. Revise paragraph (e)(2).

The revisions read as follows:

#### §720.75 Notice review period.

\* \* \* \* (b) \* \* \*

- (2)(i) Oral requests. A request for a suspension of 15 days or less may be made orally, including by telephone, to the submitter's EPA contact for that notice. Any request for a suspension exceeding 15 days must be submitted in the manner set forth in paragraph (b)(2)(ii) of this section. The running of the notice review period will be suspended upon approval of the oral request by the Director or her or his delegate.
- (ii) Written requests. Requests for suspensions exceeding 15 days must be

submitted electronically to EPA via CDX using e-PMN software. Requests for suspensions of 15 days or less may also be submitted electronically to EPA via CDX using e-PMN software. See § 720.40(a)(2)(ii) for information on how to access the e-PMN software. The running of the notice review period will be suspended upon approval of the written request by the Director or her or his delegate.

(e) \* \* \*

(2) If a manufacturer (including importer) which withdrew a notice later resubmits a notice for the same chemical substance, a new notice review period begins.

#### PART 721—[AMENDED]

■ 6. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

■ 7. In § 721.11, revise paragraphs (a), (b) introductory text, (b)(1), (2), and (3), (d), (e) and (f) to read as follows:

#### § 721.11 Applicability determination when the specific chemical identity is confidential.

- (a) A person who intends to manufacture (including import) or process a chemical substance which is described by a generic chemical name in subpart E of this part may ask EPA whether the substance is subject to the requirements of this part. EPA will answer such an inquiry only if EPA determines that the person has a bona fide intent to manufacture (including import) or process the chemical substance for commercial purposes.
- (b) To establish a bona fide intent to manufacture (including import) or process a chemical substance, the person who proposes to manufacture (including import) or process the substance must submit the request to EPA via CDX. Prior to submission to EPA via CDX, such bona fide intents to manufacture (including import) or process must be generated and completed using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software. A bona fide intent to manufacture (including import) or process must contain:
- (1) The specific chemical identity of the chemical substance that the person intends to manufacture (including import) or process.
- (2) A signed statement that the person intends to manufacture (including import) or process the chemical substance for commercial purposes.

(3) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture (including import) or process the chemical substance.

\* \* \* \* \*

(d) EPA will review the information submitted by the manufacturer (including importer) or processor under paragraph (b) of this section to determine whether that person has shown a bona fide intent to manufacture (including import) or process the chemical substance. If necessary, EPA will compare this information to the information requested for the confidential chemical substance under § 720.85(b)(3)(iii) of this chapter.

(e) If the manufacturer (including importer) or processor has shown a bona fide intent to manufacture (including import) or process the substance and has provided sufficient unambiguous chemical identity information to enable EPA to make a conclusive determination as to the identity of the substance, EPA will inform the manufacturer (including importer) or processor whether the chemical substance is subject to this part and, if so, which section in subpart E of this part applies.

(f) A disclosure to a person with a bona fide intent to manufacture (including import) or process a particular chemical substance that the substance is subject to this part will not be considered public disclosure of

be considered public disclosure of confidential business information under section 14 of the Act.

\* \* \* \*

#### PART 723—[AMENDED]

■ 8. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

- 9. In § 723.50:
- a. Revise paragraph (j)(6)(ii)(B).
- b. Remove paragraph (j)(6)(ii)(C). The revision reads as follows:

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

\* \* \* \* \* (j) \* \* \* (6) \* \* \* (ii) \* \* \*

(B) The notification must be submitted electronically to EPA via CDX as a support document to the original notification. Prior to submission to EPA via CDX, such notices must be generated and completed using the e-PMN software. See 40 CFR 720.40(a)(2)(ii) for

(d) EPA will review the information

information on how to access the e-PMN software.

\* \* \* \* \* \*

#### PART 725—[AMENDED]

■ 10. The authority citation for part 725 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, 2613 and 2625.

■ 11. In § 725.15, revise paragraphs (a)(2), (b)(2) introductory text, (b)(2)(ii) and (iii), (d), (e), (f), and (g) to read as follows:

## § 725.15 Determining applicability when microorganism identity or use is confidential or uncertain.

- (a) \* \* \*
- (2) Uncertain microorganism identity. The current state of scientific knowledge leads to some imprecision in describing a microorganism. As the state of knowledge increases, EPA will be developing policies to determine whether one microorganism is equivalent to another. Persons intending to conduct activities involving microorganisms may inquire of EPA whether the microorganisms they intend to manufacture (including import) or process are equivalent to specific microorganisms described on the Inventory, in § 725.239, or in subpart M of this part.
  - (b) \* \* \*
- (2) To establish a bona fide intent to manufacture (including import) or process a microorganism, the person who proposes to manufacture (including import) or process the microorganism must submit the request to EPA via CDX. Prior to submission to EPA via CDX, such bona fide intents to manufacture (including import) or process must be generated and completed using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to access the e-PMN software. A bona fide intent to manufacture (including import) or process must contain the following information:
- (ii) A signed statement certifying that the submitter intends to manufacture (including import) or process the microorganism for commercial purposes.
- (iii) A description of research and development activities conducted with the microorganism to date, demonstration of the submitter's ability to produce or obtain the microorganism from a foreign manufacturer, and the purpose for which the person will manufacture (including import) or process the microorganism.

\*

- submitted by the manufacturer (including importer) or processor under this paragraph to determine whether that person has shown a *bona fide* intent to manufacture (including import) or process the microorganism. If necessary, EPA will compare this information to the information requested for the confidential microorganism under § 725.85(b)(3)(iii).
- (e) In order for EPA to make a conclusive determination of the microorganism's status, the proposed manufacturer (including importer) or processor must show a bona fide intent to manufacture (including import) or process the microorganism and must provide sufficient information to establish identity unambiguously. After sufficient information has been provided, EPA will inform the manufacturer (including importer) or processor whether the microorganism is subject to this part and if so, which sections of this part apply.
- (f) If the microorganism is found on the confidential version of the Inventory, in § 725.239 or in subpart M of this part, EPA will notify the person(s) who originally reported the microorganism that another person (whose identity will remain confidential, if so requested) has demonstrated a bona fide intent to manufacture (including import) or process the microorganism and therefore was told that the microorganism is on the Inventory, in § 725.239, or in subpart M of this part.
- (g) A disclosure to a person with a bona fide intent to manufacture (including import) or process a particular microorganism that the microorganism is on the Inventory, in § 725.239, or in subpart M of this part will not be considered a public disclosure of confidential business information under section 14 of the Act.

[FR Doc. 2015–17737 Filed 7–17–15; 8:45 am]

BILLING CODE 6560-50-P

#### **DEPARTMENT OF COMMERCE**

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 648

[Docket No. 130822745-5611-02]

RIN 0648-BD64

# Fisheries of the Northeastern United States; Atlantic Surfclam and Ocean Quahoq Fisheries

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Final rule.

**SUMMARY:** This final rule implements an information collection program for the Atlantic surfclam and ocean quahog fisheries. The information collection program is intended to obtain more detailed information about individuals and businesses that hold fishery quota allocation in these individual transferable quota fisheries. This action is necessary to ensure that the Mid-Atlantic Fishery Management Council has the information needed to develop a future management action intended to establish an excessive share cap in these fisheries.

**DATES:** Effective January 1, 2016. **ADDRESSES:** Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule may be submitted to the Greater Atlantic Regional Fisheries Office and by email to *OIRA\_Submission@omb.eop.gov*, or fax to (202) 395–7285.

**FOR FURTHER INFORMATION CONTACT:** Douglas Potts, Fishery Policy Analyst, (978) 281–9341.

#### SUPPLEMENTARY INFORMATION:

#### **Background**

Section 402(a)(1) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) authorizes the Secretary of Commerce to implement an information collection program if a fishery management council determines that additional information would be beneficial for developing, implementing, or revising a fishery management plan (FMP). The Mid-Atlantic Fishery Management Council formally requested that NMFS implement an information collection program in the Atlantic surfclam and ocean quahog individual transferable quota (ITQ) fisheries. The purpose of this information collection is to better

identify individuals who hold or control ITQ allocation in these fisheries. The Council will use the information collected to inform the development of a future management action intended to establish an excessive share cap as part of the Council's Surfclam/Ocean Quahog FMP.

Currently, NMFS collects only basic information about the individuals or businesses that hold surfclam and ocean quahog ITO allocations. This information is collected at the time that an entity first acquires ITQ allocation and is not routinely verified or updated. The information collection program implemented in this action is intended to identify the specific individuals who have an ownership interest in surfclam or ocean quahog ITQ allocation through a corporation, partnership, or other business entity, or control the use of ITQ allocation through the use of longterm contracts or other agreements. This action also ensures that the ownership information on file remains up to date by modifying the procedures for receiving and maintaining an ITQ permit.

This action also makes minor corrections and clarifications to the surfclam and ocean quahog regulations.

#### **Final Measures**

Full details and background on the measures in this rule are explained in the proposed rule published on August 7, 2014 (79 FR 46233), and are not repeated here.

#### 1. Surfclam/Ocean Quahog ITQ Permit Annual Renewal

This final rule revises the regulations at § 648.74 to change the validity period for ITQ Permits. ITQ permits will now expire at the end of the year and need to be renewed annually. This annual renewal requirement better ensures that ITO-related information is kept current. Expired permits are eligible for renewal until the last day of the year for which they are needed. Permits not renewed by the deadline are considered voluntarily relinquished and will have their quota share and eligibility permanently revoked. This is commonly referred to as a "renew or lose" provision. To renew a permit, an annual ITQ permit application must be completed. The ITQ permit application form requires information such as the applicant's name, address, telephone number, and date of birth (or taxpaver identification number for businesses). ITQ permit holders are also required to verify that they are eligible to own a U.S. Coast Guard documented vessel, as defined under 46 U.S.C. 12103(b), which serves as a check of U.S.

citizenship or corporate control by U.S. citizens.

#### 2. New Surfclam/Ocean Quahog ITQ Ownership Form

This final rule implements a new ITQ ownership form that must be submitted along with the ITQ permit application form for a permit to be issued. This form is being implemented to capture detailed ownership information, such as information on bank-held shares and identification of corporate officers, major shareholders, and partners as well as any immediate family members who also hold ITQ permits. Corporations or other business entities that hold an ITQ permit will be required to identify their corporate officers and all shareholders who have a 10-percent or larger stake in the company.

#### 3. ITQ Transfer Form Changes

This action modifies the existing ITO transfer form to collect more detailed financial information about transactions in which ITQ is transferred. Information about the allocation holder is removed, as that is now collected through the ITQ permit application and the ITQ ownership form. The ITQ transfer form now clarifies whether or not a permanent transfer of ITQ quota share includes all of the cage tags for the current fishing year. This action also adds additional questions to better understand the nature of the transfer. This includes a requirement to submit total price paid for the transfer, including any fees; broker fees paid, if applicable; whether the transfer is part of a long-term (more than 1 year) contract; if so, the duration of the contract and whether the price is fixed or flexible; and any other conditions on the transfer.

### 4. Regulatory Corrections and Clarifications

This final rule revises the regulations at § 648.74(a)(1)(i) to correct a cross reference to 46 U.S.C. 12103(b), which defines the persons or entities that are eligible to own a documented vessel. This rule also corrects several cross references in § 648.14(j) to other sections of the regulations in part 648 pertaining to surfclam and ocean quahogs. Finally, the regulations at § 648.74(b)(3) specifying when the Regional Administrator may deny a transfer of ITQ quota share or cage tags have been made more detailed and clear.

The new permit requirements in this rule are effective with the start of the next fishing year on January 1, 2016. However, the new forms will be distributed in early fall to give ITQ

permit holders ample time to complete and submit the forms in order to receive their 2016 ITQ permits and 2016 cage tags before the start of the fishing year. Many ITQ shareholders choose to submit cage tags transfer requests in December, ahead of the new fishing year, so they can be processed and ready before January 1. We will continue to work to accommodate these requests for the industry.

#### **Comments and Responses**

We published a proposed rule in the Federal Register on August 7, 2014, and accepted public comments until September 8, 2014. After the comment period closed, the Council requested that we reopen the comment period to allow for additional public comment to be submitted after the proposed action was discussed at a Council meeting. In response, we published an announcement in the Federal Register on October 2, 2014 (79 FR 59472), announcing that the comment period was reopened until October 17, 2014. Altogether, we received comments from 23 individuals. Nearly all of the comments received were from the surfclam and ocean quahog industry including dealers, processors, harvesters, and surfclam and ocean quahog consumer product producers and manufacturers. All of these comments generally opposed the information collection program, and raised very similar issues. Related comments have been combined in our summary of comments and responses below. Two comments received generally supported the program, but provided no supporting information. The Mid-Atlantic Fishery Management Council submitted a comment informing us of a motion that was made at the Council meeting on October 7, 2014, regarding the information collected on the ITQ transfer form.

Comment 1: Numerous comments expressed concern that an excessive share cap is not necessary for these fisheries, and, therefore, there is no reason to collect additional information to help determine such caps.

Response: Two sections of the Magnuson-Stevens Act address the need to prevent an individual or corporation from acquiring an excessive share of fishing privileges: National Standard 4 and section 303A(c)(5)(D). Amendment 8 to the Atlantic Surfclam and Ocean Quahog FMP, which established the ITQ fishery in 1990, cited existing anti-trust laws as being sufficient to meet the requirements of National Standard 4, "that no particular individual, corporation, or other entity acquires an excessive share of such privileges."

Section 303A was added to the Act by the Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006. This section contains provisions and requirements for Limited Access Privilege Programs (LAPPS), which include ITQ programs. These added provisions include section 303A(c)(5)(D)(i), which requires LAPPs to ensure limited access privilege holders do not acquire an excessive share of the total limited access privileges in the program, by "establishing a maximum share, expressed as a percentage of the total limited access privileges, that a limited access privilege holder is permitted to hold, acquire, or use." Because the FMP does not currently include an excessive share cap expressed as a percentage of the total allocated quota, it is out of compliance with this provision of the Magnuson-Stevens Act.

This information collection program is an important part of the Council's efforts to establish a cap that meets this requirement. See the response to Comment 2 for additional rationale for why this information collection is

necessary.

Comment 2: Several comments expressed concern that we are generally collecting too much information and that it is not necessary or applicable in helping determine excessive shares. These comments expressed concern that we should not collect this information because it involves business transactions that should be confidential.

Response: We understand that this information collection includes more specific detail than is collected in other fisheries in the region. However, prior reports and analyses for these fisheries suggest this information is necessary and appropriate to determine current ownership and control of allocations in these fisheries. In the surfclam and ocean quahog fisheries, there is a series of complex corporate and business relationships involving control of quota shares. A 2002 GAO report on this ITQ program suggested that NMFS did not gather sufficient ownership information to appropriately characterize the amount of consolidation in the fishery. In 2011, NMFS and the MAFMC contracted an economic consulting firm to examine and report on potential excessive share caps in this fishery (Mitchell, Peterson and Willig. Recommendations for Excessive Share Limits in the SCOQ Fisheries. May 3, 2011), and subsequently convened a panel of independent reviewers to evaluate the report (Summary of Findings by the Center for Independent Experts Regarding Setting Excessive

Share Limits for ITQ Fisheries; www.nefsc.noaa.gov/publications/crd/ crd1122/). In a series of public meetings, a special Council workgroup met and considered the recommendations of these reports, reviewed how ownership information is collected in other fisheries around the country, reviewed the information currently collected in this fishery, and then devised a suite of data elements that would provide the information the Council would need when developing an excessive shares cap. These recommendations were detailed in a white paper that was considered and approved by the Council. Without the additional information this action will collect, the Council may not have the information necessary to make informed decisions on excessive share caps. When the Council ultimately establishes an excessive shares cap, it is possible that not all of these data elements will be necessary to effectively monitor the cap. At that time, this collection will be reevaluated, and data elements may be added, removed, or modified to address the specific information needed to monitor the cap.

We agree that some business transactions are confidential. Pursuant to section 402(b) of the Magnuson-Stevens Act, information submitted in compliance with the Act is confidential, and would not be distributed or made publicly available. These confidentiality requirements of the Magnuson-Stevens Act apply to information collected as a result of this action. Therefore, the collected information may be used to conduct analysis by NMFS, or Council staff who are subject to confidentiality agreements. Results of this analysis could only be presented in an aggregate form, which protects any confidential information.

Comment 3: Nearly all of the comments received against this action were opposed to the provision that ITQ quota share could be considered permanently relinquished if the shareholder's ITQ permit is not renewed before the end of the fishing year. These comments explain that banks and other lending institutions hold much of the ITQ quota share in the surfclam and ocean quahog fisheries. Commenters expressed concern that lenders could view the potential loss of quota share as an unacceptable investment risk. Commenters stated this could result in the banks leaving the industry and discontinuing investment in the Atlantic surfclam and ocean quahog fisheries. These commenters further asserted that it is too easy to make an administrative error of not renewing a

permit which would result in unfair loss of valuable ITQ quota share.

Response: NMFS understands that there are concerns with losing the fishing rights associated with ITQ quota share if a permit is not renewed. However, based on the comments received, there appears to be a misunderstanding of how this provision would function. While a number of these comments seemed to be under the impression the rights to a permit would be lost immediately following the permit's expiration date, this is not the case. To clarify, an ITQ permit and quota share are not lost the day the permit expires. Although the permit cannot be used to harvest fish after it has expired, the applicant is eligible to renew the permit for the entire following year before the permit would be considered surrendered. For example, if an ITQ permit expires on December 31, 2015, the applicant has until December 31, 2016, to renew the permit before it is considered surrendered. It would not be surrendered when it expires on December 31, 2015.

All limited access vessel permits in the Greater Atlantic Region have been subject to these renew-or-lose provisions since they were implemented in the mid-1990s. The Golden Tilefish Individual Fishing Quota program has operated under renew-or-lose provisions for tilefish quota share since the program's inception in 2010. If a permit is not renewed, NMFS makes multiple attempts to notify the permit holder of the need to renew the permit well before the deadline. Permanent loss of fishing rights has occurred for these other fisheries. However, loss of the right to a permit is rarely due to a clerical error such as simply forgetting to renew a permit. We believe such instances are infrequent given the system that provides a year to renew after permit expiration and multiple reminders prior

to loss of fishing rights. Further, the ITQ permit must be current and valid in order for ITQ to be traded or for fishing activity to occur using ITQ. In 2014, there were 41 ocean quahog ITQ permits with quota share and 70 surfclam ITQ permits with quota share. Of these 111 ITQ permits, all but 15 transferred allocation, used cage tags to land clams, or otherwise participated in the fishery in a manner that will now require a current valid permit. The majority of those permits not used in 2014, were used in the preceding two years. Therefore, it is likely that most if not all permits will be renewed each year in order for ITQ shareholders to continue participating in the fishery as they have in previous years. As a result,

there would be little to no threat of an ITQ shareholder permanently losing his/her quota share.

Certainly, lenders will continue to evaluate investment risk as it relates to these fisheries. We believe it unlikely that investors will find the "renew or lose" provision to be an additional risk that would preclude investment.

Comment 4: The Council submitted a comment informing us of a motion approved at the October 2014 Council meeting to request we remove much of the information to be collected on the

ITQ transfer form.

Response: While the motion was supported by a majority of the Council members present, the vote was not unanimous and there were members who expressed a strong interest in having this information available when they consider an excessive shares cap. Removing these fields from the ITQ transfer form would be contrary to the recommendations in the white paper prepared by the Council's special workgroup and the 2011 report Economic Guidelines for Excessive Share Limits in the Surfclam and Ocean Quahog Fisheries. Currently, no information is collected on the financial aspects of allocation transfers in the surfclam and ocean quahog ITQ fishery. Similar programs around the country routinely collect information about the price paid for allocation. This information can provide valuable insight into the market for quota or longterm contracts and agreements that would not otherwise be apparent. These additional details about transfers can illuminate situations where individuals or companies exert effective control over ITQ allocation, even if they do not directly hold the quota share.

As mentioned above in the response to Comment 2, we anticipate that the specific data elements will be reevaluated and revised when an excessive share cap is implemented. For these reasons, we continue to support the inclusion of all of the proposed elements of this information collection program, at least for the short term. Therefore, this action implements the ITQ transfer form as described in the proposed rule.

#### **Changes From Proposed Rule**

There are no substantive changes from the measures described in the proposed rule. The preamble to the proposed rule explained that banks holding quota share as collateral on a loan would not need to provide as much detail about ownership if the borrower maintains a valid ITQ permit and the bank could only transfer quota share or cage tags to the borrower. However, the regulatory

text in the proposed rule did not fully reflect these requirements. These requirements have been added at § 648.74(a)(1)(ii)(C) and (b)(3) in this final rule to reflect these provisions as they were described in the preamble of the proposed rule.

#### Classification

The Administrator, Greater Atlantic Region, NMFS, determined that this action is necessary for the conservation and management of the Atlantic surfclam and ocean quahog fishery and that it is consistent with the Magnuson-Stevens Fishery Conservation and Management Act and other applicable laws

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for this certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

This final rule contains a change to a collection-of-information requirement subject to the Paperwork Reduction Act (PRA) and which has been approved by the Office of Management and Budget (OMB) under OMB Control Number 0648-0240: Northeast Region Surfclam and Ocean Quahog Individual Transferable Quota (ITQ) Administration. The public reporting burden is estimated to average 5 minutes per response for the application for surfclam/ocean quahog ITQ permit; 60 minutes per response for new entrants completing the surfclam/ocean quahog ITQ ownership form and to average 5 minutes per response when the form is pre-filled for renewing entities; and the application to transfer surfclam/ocean quahog ITQ are estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The costs burden associated for all of the requirements is \$.49 per submission for postage. Send comments regarding these burden estimates or any other aspect of this data collection, including suggestions for reducing the burden, to NMFS (see **ADDRESSES**) and by email to *OIRA* 

Submission@omb.eop.gov, or fax to 202–395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

#### List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: July 14, 2015.

#### Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 648 is amended as follows:

### PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 et seq.

■ 2. In § 648.14, revise paragraphs (j)(1)(ii), (j)(2)(i), (j)(3)(v), (j)(3)(vi), (j)(5)(ii), (j)(5)(iv), (j)(5)(v), (j)(6)(ii), and (j)(6)(iii) to read as follows:

#### § 648.14 Prohibitions.

\* \* \* \* \* \* \* \* \* \* \* \*

(1) \* \* \*

(ii) Shuck surfclams or ocean quahogs harvested in or from the EEZ at sea, unless permitted by the Regional Administrator under the terms of § 648.75.

(2) Transfer and purchase. (i) Receive for a commercial purpose other than solely for transport on land, surfclams or ocean quahogs harvested in or from the EEZ, whether or not they are landed under an allocation under § 648.74, unless issued a dealer/processor permit under this part.

(3) \* \* \*

(v) Possess an empty cage to which a cage tag required by § 648.77 is affixed, or possess any cage that does not contain surfclams or ocean quahogs and to which a cage tag required by § 648.77 is affixed.

(vi) Land or possess, after offloading, any cage holding surfclams or ocean quahogs without a cage tag or tags required by § 648.77, unless the person can demonstrate the inapplicability of the presumptions set forth in § 648.77(h).

\* \* \* \* \*

(ii) Land unshucked surfclams and ocean quahogs harvested in or from the EEZ within the Maine mahogany quahog zone in containers other than cages from vessels capable of carrying cages unless, with respect to ocean quahogs, the vessel has been issued a Maine mahogany quahog permit under this part and is not fishing for an individual allocation of quahogs under § 648.74.

- (iv) Offload unshucked ocean quahogs harvested in or from the EEZ within the Maine mahogany quahog zone from vessels not capable of carrying cages, other than directly into cages, unless the vessel has been issued a Maine mahogany quahog permit under this part and is not fishing for an individual allocation of quahogs under § 648.74.
- (v) Land or possess ocean quahogs harvested in or from the EEZ within the Maine mahogany quahog zone after the effective date published in the Federal Register notifying participants that Maine mahogany quahog quota is no longer available for the respective fishing year, unless the vessel is fishing for an individual allocation of ocean quahogs under § 648.74.

(6) \* \* \*

- (ii) Surfclams or ocean quahogs landed from a trip for which notification was provided under § 648.15(b) or § 648.74(b) are deemed to have been harvested in the EEZ and count against the individual's annual allocation, unless the vessel has a valid Maine mahogany quahog permit issued pursuant to § 648.4(a)(4)(i) and is not fishing for an individual allocation under § 648.74.
- (iii) Surfclams or ocean quahogs found in cages without a valid state tag are deemed to have been harvested in the EEZ and are deemed to be part of an individual's allocation, unless the vessel has a valid Maine mahogany quahog permit issued pursuant to  $\S 648.4(a)(4)(i)$  and is not fishing for an individual allocation under § 648.74; or, unless the preponderance of available evidence demonstrates that he/she has surrendered his/her surfclam and ocean quahog permit issued under § 648.4 and he/she conducted fishing operations exclusively within waters under the jurisdiction of any state. Surfclams and ocean quahogs in cages with a Federal tag or tags, issued and still valid pursuant to this part, affixed thereto are deemed to have been harvested by the individual allocation holder to whom the tags were issued or transferred under § 648.74 or § 648.77(b).

■ 3. Revise § 648.74 to read as follows:

#### § 648.74 Individual Transferable Quota (ITQ) Program.

(a) Annual individual allocations. Each fishing year, the Regional Administrator shall determine the initial annual allocation of surfclams and ocean quahogs for the next fishing year for each ITQ permit holder holding ITQ quota share pursuant to the requirements of this section. For each species, the initial allocation for the next fishing year is calculated by multiplying the quota share percentage held by each ITQ permit holder as of the last day of the previous fishing year in which quota shareholders are permitted to permanently transfer quota share percentage pursuant to paragraph (b) of this section (i.e., October 15 of every year), by the quota specified by the Regional Administrator pursuant to § 648.72. The total number of bushels of annual allocation shall be divided by 32 to determine the appropriate number of cage tags to be issued or acquired under § 648.77. Amounts of annual allocation of 0.5 cages or smaller created by this division shall be rounded downward to the nearest whole number, and amounts of annual allocation greater than 0.5 cages created by this division shall be rounded upward to the nearest whole number, so that annual allocations are specified in whole cages.

(1) Surfclam and ocean quahog ITQ permits. Surfclam and ocean quahog ITQ allocations shall be issued in the form of annual ITQ permits. The ITQ permit shall specify the quota share percentage held by the ITQ permit holder and the annual allocation in cages and cage tags for each species.

(i) Eligibility. In order to be eligible to hold a surfclam or ocean quahog ITQ permit, an individual must be eligible to own a documented vessel under the terms of 46 U.S.C. 12103(b).

(ii) Application—(A) General. Applicants for a surfclam or ocean quahog ITQ permit under this section must submit a completed ITQ permit application and a completed ITQ ownership form on the appropriate forms obtained from NMFS. The ITQ permit application and ITQ ownership form must be filled out completely and signed by the applicant. The Regional Administrator will notify the applicant of any deficiency in the application.

(B) Renewal applications. Applications to renew a surfclam or ocean quahog ITQ permit must be received by November 1 to be processed in time for permits to be issued by December 15, as specified in paragraph (a)(1)(iii) of this section. Renewal applications received after this date may

not be approved, and a new permit may not be issued before the start of the next fishing year. An ITQ permit holder must renew his/her ITQ permit(s) on an annual basis by submitting an application and an ownership form for such permit prior to the end of the fishing year for which the permit is required. Failure to renew a surfclam or ocean quahog ITQ permit in any fishing year will result in any surfclam or ocean quahog ITQ quota share held by that ITQ permit holder to be considered abandoned and relinquished as specified in paragraph (a)(1)(ix) of this section.

(C) Lenders Holding ITQ Quota Share as Collateral. A bank or other lender that holds ITQ quota share as collateral on a loan may be allowed to provide less detailed information on the ITQ ownership form under the following conditions.

(1) The lender certifies that the ITQ quota share is held solely as collateral on a loan and the lender does not exert any control over the use of the annual

allocation of cage tags.

(2) The lender identifies the borrower, and the borrower maintains a valid ITQ permit including all required ownership information.

(3) The lender may only transfer quota share or cage tags to the identified borrower. The borrower could then transfer the quota share or cage tags to

another party, if desired.

(iii) Issuance. Except as provided in subpart D of 15 CFR part 904, and provided an application for such permit is submitted by November 1, as specified in paragraph (a)(1)(ii)(B) of this section, NMFS shall issue annual ITQ permits on or before December 15, to allow allocation owners to purchase cage tags from a vendor specified by the Regional Administrator pursuant to § 648.77(b).

(iv) Duration. An ITQ permit is valid through December 31 of each fishing year unless it is suspended, modified, or revoked pursuant to 15 CFR part 904, or revised due to a transfer of all or part of the ITQ quota share or cage tag allocation under paragraph (b) of this section.

(v) Alteration. An ITQ permit that is altered, erased, or mutilated is invalid.

(vi) Replacement. The Regional Administrator may issue a replacement permit upon written application of the annual ITQ permit holder.

(vii) Transfer. The annual ITQ permit is valid only for the person to whom it is issued. All or part of the ITQ quota share or the cage tag allocation specified in the ITQ permit may be transferred in accordance with paragraph (b) of this section.

(viii) Fee. The Regional Administrator may, after publication of a fee notification in the **Federal Register**, charge a permit fee before issuance of the permit to recover administrative expenses. Failure to pay the fee will preclude issuance of the permit.

(ix) Abandonment or voluntary relinquishment. Any ITQ permit that is voluntarily relinquished to the Regional Administrator, or deemed to have been voluntarily relinquished for failure to renew in accordance with paragraph (a)(1)(ii) of this section, shall not be reissued or renewed in a subsequent year, except as specified in paragraph (a)(1)(x) of this section.

(x) Transitional grace period. A surfclam or ocean quahog quota share holder who does not submit a complete application for an ITQ permit before the end of the 2016 fishing year, may be granted a grace period of up to one year to complete the initial application process, and be issued an ITQ permit, before the quota share is considered permanently relinquished. If an individual is issued a 2016 ITQ permit, but fails to renew that ITQ permit before the end of the 2017 fishing year, the Regional Administrator may allow a grace period until no later than July 1, 2018, to complete the renewal process and retain the permit. A permit holder may not be issued cage tags or transfer quota share until a valid ITQ permit is issued. Failure to complete the ITQ

permit application or renewal process, and be issued a valid ITQ permit before the end of such a grace period would result in the ITQ permit and any associated ITQ quota share being permanently forfeit.

(2) [Reserved]

(b) Transfers—(1) Quota share percentage. Subject to the approval of the Regional Administrator, part or all of a quota share percentage may be transferred in the year in which the transfer is made, to any person or entity with a valid ITQ permit under paragraph (a) of this section. Approval of a transfer by the Regional Administrator and for a new ITQ permit reflecting that transfer may be requested by submitting a written application for approval of the transfer and for issuance of a new ITQ permit to the Regional Administrator at least 10 days before the date on which the applicant desires the transfer to be effective, in the form of a completed transfer form supplied by the Regional Administrator. The transfer is not effective until the new holder receives a new or revised ITO permit from the Regional Administrator reflecting the new quota share percentage. An application for transfer may not be made between October 15 and December 31 of each year.

(2) Cage tags. Cage tags issued pursuant to § 648.77 may be transferred at any time, and in any amount subject to the restrictions and procedure

specified in paragraph (b)(1) of this section; provided that application for such cage tag transfers may be made at any time before December 10 of each year. The transfer is effective upon the receipt by the transferee of written authorization from the Regional Administrator.

(3) Denial of ITQ transfer application. The Regional Administrator may reject an application to transfer surfclam or ocean quahog ITQ quota share or cage tags for the following reasons: The application is incomplete; the transferor or transferee does not possess a valid surfclam or ocean quahog ITQ permit for the appropriate species; the transfer is not allowed under paragraph (a)(1)(ii)(C)(3) of this section; the transferor's or transferee's surfclam or ocean quahog ITQ permit has been sanctioned pursuant to an enforcement proceeding under 15 CFR part 904; or any other failure to meet the requirements of this subpart. Upon denial of an application to transfer ITQ allocation, the Regional Administrator shall send a letter to the applicant describing the reason(s) for the denial. The decision by the Regional Administrator is the final decision of the Department of Commerce; there is no opportunity for an administrative appeal.

[FR Doc. 2015-17678 Filed 7-17-15; 8:45 am]

BILLING CODE 3510-22-P

### **Proposed Rules**

#### Federal Register

Vol. 80, No. 138

Monday, July 20, 2015

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

#### **DEPARTMENT OF TRANSPORTATION**

#### **Federal Aviation Administration**

#### 14 CFR Part 25

[Docket No. FAA-2015-2490]

### Bird Strike Requirements for Transport Category Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Request for comments on bird strike requirements for transport category airplanes.

**SUMMARY:** This document solicits public comments on the need for, and the possible scope of, changes to the bird strike certification requirements for transport category airplanes. The FAA is not currently proposing a specific regulatory action. The purpose of this request is to gather comments from airplane manufacturers and other interested parties on this subject.

**DATES:** Send comments by November 17, 2015.

Comments to: *Todd.Martin@faa.gov*. **ADDRESSES:** Send comments, identified by Docket No. FAA–2015–2490, using any of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov and follow the online instructions for sending your comments electronically.
- Mail: Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- Hand Delivery or Courier: Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking

process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

Docket: Background documents or comments received may be read at http://www.regulations.gov at any time. Follow the online instructions for accessing the docket or go to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

#### FOR FURTHER INFORMATION CONTACT:

Todd Martin, Airframe and Cabin Safety Branch, ANM–115, FAA, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone (425) 227–1178; facsimile (425) 227–1232; email *Todd.Martin@faa.gov.* 

#### SUPPLEMENTARY INFORMATION:

#### **Comments Invited**

The FAA invites interested persons to comment on the need for, and the possible scope of, changes to the bird strike requirements for transport category airplanes by submitting written data, views, or arguments as they may desire. We have conducted a review of bird strike data, and we are considering whether to revise the requirements, as described in this document. We invite comments relating to the technical or economic impact that might result from any of the rule changes discussed herein, as well as any alternative suggestions. Substantive comments should be accompanied by estimates of their economic impact if possible. All comments received by the closing date for comments will be considered by the FAA.

#### **Background**

Bird strike requirements for transport category airplanes are specified in Title 14, Code of Federal Regulations (14 CFR), part 25, and vary depending on the structural component being evaluated. Section 25.775 requires windshields and their supporting structure withstand, without penetration, impact with a four-pound bird at  $V_{\rm C}$  (design cruising speed) at sea level. This regulation has been in place

and is unchanged since part 25 was introduced in 1965.

Section 25.631 requires the empennage structure be designed to assure continued safe flight after impact with an eight-pound bird at  $V_{\rm C}$  at sea level, including consideration of control system elements. This regulation was introduced at Amendment 25–23 (effective May 8, 1970) as a result of the 1962 Vickers Viscount accident, which was caused by impact with a swan, estimated to weigh between 12 and 17 pounds, that damaged the horizontal stabilizer and elevator.

Section 25.571 considers the rest of the airframe and requires the airplane be capable of continued safe flight after impact with a four-pound bird at  $V_{\rm C}$  at sea level, and .85  $V_{\rm C}$  at 8000 feet. This regulation was introduced at Amendment 25–45 (effective December 1, 1978) with some changes in the speed definition since then. A speed criterion is provided at 8000 feet to ensure adequate bird strike resistance capability up to that altitude.

In 1993, the FAA was developing a notice of proposed rulemaking to establish a consistent eight-pound bird requirement for all structures. The FAA decided instead to task the Aviation Rulemaking Advisory Committee (ARAC) to evaluate the bird strike requirements and make recommendations. The working group completed its deliberations in 2003 without reaching agreement. All members in the working group, except the FAA, favored reducing the eightpound bird requirement in § 25.631 to four pounds, thus establishing a consistent four-pound bird requirement for all structures. Other changes to the requirements were considered by the group, but none were adopted. The working group report is available at: http://www.faa.gov/regulations policies/rulemaking/committees/ documents/media/TAEgshT1-031593.pdf.

More recently, the National Transportation Safety Board (NTSB) issued the following Safety Recommendation to the FAA as a result of a fatal Cessna 500 accident that occurred in 2008: A–09–072, "Revise the bird-strike certification requirements for Part 25 airplanes so that protection from in-flight impact with birds is consistent across all airframe structures. Consider the most current military and

civilian bird-strike database information and trends in bird populations in drafting this revision."

To determine the adequacy of current bird strike certification requirements, the FAA reviewed a number of reports, including the 2003 ARAC report, and other reports that address bird populations. We also reviewed recent bird strike event data and compared the energy levels of bird strike events to the energy levels prescribed in the current requirements. We found numerous bird strike events in which the energy level

exceeded that specified in current part 25 requirements.

#### Sample of Bird Strike Event Data

The severity of a bird strike depends primarily on kinetic energy, which is proportional to mass times velocity squared. Bird strikes involving birds greater than four pounds occur often, but usually at speeds below the design cruising speed,  $V_{\rm C}$ . Therefore, the energy level of such strikes is usually below that specified in current

requirements. However, in some cases, that energy level is exceeded.

In each of the bird strike events shown below, the FAA estimates that the energy level of the strike exceeded that specified in current requirements. This is not an exhaustive list; these are just some examples of events that occurred in the US since the 2008 Cessna accident. For these events, we estimated the energy level of the event and compared it to the current fourpound bird requirement specified in §§ 25.571 and 25.775.

### RECENT EXAMPLES OF BIRD STRIKE EVENTS IN WHICH THE ENERGY LEVEL EXCEEDED THE CURRENT AIRPLANE-LEVEL STANDARD

[4 Pound Bird at V<sub>C</sub>]

1. Energy level approximately 1.8 times current certification standard:

Date: 4 March 2008.

Aircraft: Cessna Citation Model 500.

Airport: Wiley Post (OK).

Phase of Flight: Climb (3,100' MSL (mean sea level)).

Estimated Airspeed: 198 KTAS (knots true airspeed).

Effect on Flight: Crashed.

Wildlife Species: American white pelican (mean weight 12.5 lb.). Multiple birds.

Damage: Aircraft destroyed. Five fatalities. Shortly after takeoff, the airplane flew through a flock of birds. There was no evidence that any pieces of the airplane separated in flight. Bird residues were identified on the right horizontal stabilizer and the right side of the vertical stabilizer.

2. Energy level approximately 2.3 times current certification standard:

Date: 8 April 2008.

Aircraft: Bombardier Challenger 600.

Airport: Colorado Springs (CO).

Phase of Flight: Climb (8,000' MSL).

Estimated Airspeed: 260 KTAS.

Effect on Flight: Precautionary landing.

Wildlife Species: American white pelican (mean weight 12.5 lb.). Multiple birds.

Damage: One bird penetrated the fuselage below the cockpit windows, through the forward pressure bulkhead and into the cockpit. Both engines ingested at least 1 bird. The #1 engine had fan damage; the #2 engine lost power and had a dented inlet lip. Noise and wind in the flightdeck. The left engine had high vibration levels. The fuselage skin and forward pressure bulkhead were penetrated and contained bird matter. The left engine thrust reverser torque box assembly and pylon tracks were bent, and the engine cowl supports were broken.

3. Energy level approximately 1.5 times current certification standard:

Date: 3 February 2009.

Aircraft: Boeing 757-200.

Airport: Denver International (CO).

Phase of Flight: Climb (7,500' MSL).

Estimated Airspeed: 270 KTAS (Airspeed not recorded. Airspeed estimate assumes airplane was flying 10 knots below 250 KIAS speed restriction. At 7500' MSL, 250 KIAS is approximately equal to 280 KTAS).

Effect on Flight: Emergency landing.

Wildlife Species: Bald eagle (mean weight 10.4 lb.). Single bird.

Damage: Bird hit right side of engine cowling making a large dent before entering the engine where it damaged all fan blades.

4. Energy level approximately 4.2 times current certification standard:

Date: 10 August 2010.

Aircraft: Embraer 145.

Airport: Salt Lake City International (UT).

Phase of Flight: Approach (11,000' MSL).

Estimated Airspeed: 290 KTAS.

Effect on Flight: Landed using back up radio.

Wildlife Species: American white pelican (mean weight 12.5 lb.). Multiple birds.

Damage: Birds punctured the nose of the aircraft between the nose cone and windshield. The birds damaged the skin, stringers, structural mounts and various avionics equipment. One bird penetrated the airplane's skin and entered the forward avionics bay. The captain lost a number of his primary instruments.

5. Energy level approximately 2.3 times current certification standard:

Date: 08 November 2010.

Aircraft: Bombardier DHC-8.

Airport: Los Angeles International (CA).

Phase of Flight: Approach (6,600' MSL).

Estimated Airspeed: 243 KTAS.

Effect on Flight: Emergency landing.

Wildlife Species: Common loon (mean weight 9.1 lb.). Single bird.

### RECENT EXAMPLES OF BIRD STRIKE EVENTS IN WHICH THE ENERGY LEVEL EXCEEDED THE CURRENT AIRPLANE-LEVEL STANDARD—Continued

[4 Pound Bird at V<sub>C</sub>]

Damage: Bird impact resulted in a 12-inch hole in the right wing leading edge, and internal structural damage to the right wing and fuel tank.

6. Energy level approximately 1.2 times current certification standard:

Date: 15 November 2010. Aircraft: Embraer 170.

Airport: Minneapolis-St. Paul International (MN).

Phase of Flight: Climb (5000' MSL). Estimated Airspeed: 270 KTAS.

Effect on Flight: Precautionary landing.

Wildlife Species: Snow goose (mean weight 5.8 lb.). Multiple birds.

Damage: Radome, engine, fuselage. Autothrottle system disengaged. First officer's primary flight display had alert flags for the indicated airspeed and altitude parameters. Substantial damage to the radome and its underlying structural components. The forward pressure bulkhead web contained a dent and puncture. The left engine compressor section was damaged.

7. Energy level approximately 1.4 times current certification standard:

Date: 01 November 2011.

Aircraft: Airbus 320.

Airport: Minneapolis-St Paul International (MN).

Phase of Flight: Climb (3300' MSL). Estimated Airspeed: 220 KTAS.

Effect on Flight: Precautionary landing, emergency declared.

Wildlife Species: Tundra swan (mean weight 14.8 lb.). Single bird.

Damage: Bird hit right side of nose. Substantial damage to the radome, nose, #2 engine and forward pressure bulkhead.

8. Energy level approximately 1.8 times current certification standard:

Date: 25 October 2012.

Aircraft: Boeing 757–200.

Airport: Boise Air Terminal (ID).

Phase of Flight: Climb (14,000' MSL).

Estimated Airspeed: 390 KTAS.

Effect on Flight: Precautionary landing.

Wildlife Species: Snow goose (mean weight 5.8 lb.). Multiple birds.

Damage: The radome was penetrated and the bulkhead was punctured. There was extensive damage to the #2 engine.

9. Energy level approximately 2.2 times current certification standard:

Date: 12 October 2013.

Aircraft: Cessna 525.

Airport: Lincoln (NE).

Phase of Flight: Climb (6400' MSL).

Estimated Airspeed: 220 KTAS.

Effect on Flight: Precautionary landing.

Wildlife Species: American white pelican (mean weight 12.5 lb.). Single bird.

Damage: Substantial damage to the outer right wing spar.

These event data, including estimated airplane altitude and airspeed, are derived from the following reports:

1. The FAA Wildlife Strike Database, available at: http://www.faa.gov/airports/airport\_safety/wildlife.

2. The FAA Aviation Safety Information Analysis and Sharing (ASIAS) System, available at: http://www.asias.faa.gov. This includes the FAA Accident/Incident Data System, and the NTSB Aviation Accident and Incident Data System.

3. National Transportation Safety Board. 2009. Aircraft Accident Report: Crash of Cessna 500, N113SH, Following an In-Flight Collision with Large Birds, Oklahoma City, Oklahoma, March 4, 2008. Aircraft Accident Report NTSB/AAR-09/05. Washington, DC.

In addition to the events listed above, there are hundreds of examples of bird strike events in which the energy level did not exceed current requirements, but substantial damage to the airframe occurred. In addition to structural

damage, major damage to electrical, flight control and fuel systems has occurred, and there have been dozens of incidents in which the flight deck was penetrated.

#### **Bird Population Trends**

The bird strike threat has increased, especially the threat due to larger birds. In a report commissioned by the FAA, Assessment of Wildlife Strike Risk to Airframes; Herricks, Mankin, and Shaeffer; December 2002; the authors wrote, "The findings of this report, supported by other literature, indicate that future operational environments for aircraft can be expected to contain larger numbers of birds, and larger numbers of birds with weights greater than four pounds."

According to Wildlife Strikes to Civil Aircraft in the United States, 1990– 2013, US Depts. of Transportation and Agriculture, July 2014: "Many populations of large bird and mammal species commonly involved in strikes have increased markedly in the last few decades and adapted to living in urban environments, including airports. For example, the resident (non-migratory) Canada goose population in the USA and Canada increased from about 0.5 million to 3.8 million from 1980 to 2013 (Dolbeer et al. 2014, U.S. Fish and Wildlife Service. 2013). During the same time period, the North American snow goose population increased from about 2.1 million to 6.6 million birds (U.S. Fish and Wildlife Service. 2013). Other large-bird species that have shown significant population increases from 1980 to 2012 include bald eagles (6.4 percent annual rate of increase), wild turkeys (9.5 percent), turkey vultures (2.7 percent), American white pelicans (7.9 percent), double-crested cormorants (6.1 percent), sandhill cranes (5.9 percent), great blue herons (1.2 percent), and ospreys (3.0 percent, Sauer et al. 2014). Dolbeer and Begier (2013) examined the estimated population

trends and numbers for the 21 species of birds in North America with mean body masses greater than 4 pounds and at least 10 strikes with civil aircraft from 1990–2012. Of these 21 species, 17 had shown population increases from 1990–2012 with a net gain of 17 million birds. Previous research had documented that 13 of the 14 bird species in North America with mean body masses greater than 8 pounds showed significant population increases from 1970 to the early 1990s (Dolbeer and Eschenfelder 2003)."

#### **Airspeed Information**

In the U.S., § 91.117 prescribes a speed restriction of 250 knots indicated airspeed below 10,000 feet mean sea level. The 250 knot speed restriction is also in place in Mexico and Canada, and in many areas around the world, but not everywhere. Where this speed restriction is in place, it provides a significant safety benefit with respect to bird strikes.

While deviations to this speed restriction are allowed, and the requirement is not global, it does indicate that limiting airspeed below 10,000 feet is operationally feasible for transport category airplanes. Indeed, to meet current bird strike criteria, some manufacturers specify relatively low  $V_{MO}$  and  $V_{C}$  airspeeds up to 8000 feet, that increase above that altitude. These speed "cutbacks" at lower altitudes are beneficial for three reasons: (1) They increase safety by reducing the energy of any bird strike that occurs below 8000 feet, (2) they apply to all airspace, not just those areas covered by US operating regulations, or those of other countries, and (3) they reduce the bird strike speeds to which the airplane must be designed.

To encourage these speed cutbacks, we believe establishing the bird strike speed criteria based on  $V_{MO}$  rather than  $V_{C}$  may be warranted. While most structures rules are based on  $V_{C}$ , allowing these very speed-dependent criteria to be based on  $V_{MO}$  may make the establishment of speed cutbacks easier to achieve.

#### **Summary of FAA Findings**

Our review of bird strike event data and bird population data indicates the following:

- Bird strikes have occurred and will continue to occur at energy levels that exceed the level provided by current requirements.
- 2. Numerous bird strikes have resulted in penetration into the flight deck, mostly below the windshield, even at energy levels below current requirements. Penetration of the cockpit

- obviously introduces a number of significant risks to the airplane. Currently, there is no requirement that specifically prohibits penetration of the flight deck through structure other than the windshield.
- 3. The bird strike threat has increased, especially the threat due to larger birds. Therefore, current fleet history may not be indicative of what to expect in the future
- 4. Bird strike events often involve more than one bird. Such multiple bird strikes may result in structural damage in several areas, pilot disorientation, engine failure and systems failures. Any one of these effects can significantly reduce the controllability of the airplane. Sections 25.571 and 25.631 assume a single bird strike, rather than multiple bird strikes. The FAA believes that this single bird strike approach is an adequate approach for airframe structure as long as the single bird strike criteria are robust. By showing the structure capable of withstanding a significant bird strike in any one area. a bird strike to that area should not compound the hazard from strikes in other areas.
- 5. Limiting airspeed below 10,000 feet is operationally feasible for transport category airplanes. Bird strike data indicate numerous damaging bird strikes have occurred above 8000 feet, but above 10,000 feet, bird strikes are rare. Therefore, expanding the envelope above 8000 feet, but limiting it at 10,000 feet, may be warranted.
- 6. Establishing reduced  $V_{\rm MO}$  and  $V_{\rm C}$  airspeeds at lower altitudes provides a significant safety benefit with respect to bird strikes.

#### **Request for Comments**

The FAA invites interested persons to comment on the need for, and the possible scope of, changes to the bird strike requirements for transport category airplanes by submitting written data, views, or arguments as they may desire. We invite comments relating to the technical or economic impact that might result from any considerations discussed herein, as well as any alternative suggestions. In particular, we invite information, comments, and opinion on the following questions:

- 1. Should the bird weight requirement be applied consistently across the airplane?
- 2. Should the bird weight requirement be increased, to eight pounds or some other value?
- 3. Should a "no-penetration" requirement be applied to the entire fuselage, not just the windshields?
- 4. Should the bird strike criteria be expanded to 10,000 feet?

- 5. Should the 0.85 speed reduction factor at 8000 feet, currently specified in § 25.571, be removed?
- 6. Should the speed criterion for bird strikes be based on  $V_{MO}$  rather than  $V_{C}$ ?

#### Conclusion

This document solicits public comments on the need for, and the possible scope of, changes to the bird strike certification requirements for transport category airplanes.

#### List of Subjects in 14 CFR Part 25

Aircraft, Aircraft safety.

Issued in Renton, Washington, on June 25, 2015.

#### Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–17404 Filed 7–17–15; 8:45 am] **BILLING CODE 4910–13–P** 

#### **DEPARTMENT OF TRANSPORTATION**

#### **Federal Aviation Administration**

#### 14 CFR Part 39

[Docket No. FAA-2015-2462; Directorate Identifier 2014-NM-224-AD]

#### RIN 2120-AA64

### Airworthiness Directives; The Boeing Company Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 737-100, -200, -200C, -300, -400, -500 series airplanes. This proposed AD was prompted by reports of cracked antenna support channels, skin cracking underneath the number 2 very high frequency (VHF) antenna, and cracking in the frames attached to the internal support structure. This proposed AD would require repetitive inspections to determine the condition of the skin and the internal support structure, and follow-on actions including corrective action as necessary. We are proposing this AD to detect and correct skin cracking of the fuselage which could result in separation of the number 2 VHF antenna from the airplane and rapid depressurization of the cabin.

**DATES:** We must receive comments on this proposed AD by September 3, 2015.

**ADDRESSES:** You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the instructions for submitting comments.
  - Fax: 202-493-2251.
- Mail: U.S. Department of Transportation, Docket Operations, M– 30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- Hand Delivery: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet https:// www.myboeingfleet.com. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at http:// www.regulations.gov by searching for and locating Docket No. FAA-2015-2462.

#### **Examining the AD Docket**

You may examine the AD docket on the Internet at http://www.regulations.gov by searching for and locating Docket No. FAA-2015-2462; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

#### FOR FURTHER INFORMATION CONTACT:

Wayne Lockett, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6447; fax: 425-917-6590; email: wayne.lockett@faa.gov.

#### SUPPLEMENTARY INFORMATION:

#### **Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES**  section. Include "Docket No. FAA–2015–2462; Directorate Identifier 2014–NM–224–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to http://www.regulations.gov, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

#### Discussion

We have received reports of cracked antenna support channels, skin cracking underneath the number 2 VHF antenna, and cracking in the frames attached to the internal support structure. The cracking is caused when the nose gear is let down, resulting in turbulent airflow around the antenna. The turbulent airflow causes vibration in the antenna, which results in the skin, as well as the internal support structure and frames, to crack due to fatigue. This condition, if not corrected, could result in separation of the antenna from the airplane and rapid depressurization of the cabin.

### **Related Service Information Under 1 CFR Part 51**

We reviewed Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014. The service information describes procedures for repetitive inspections to determine the condition of the skin and the internal support structure, and follow-on actions including corrective action as necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section of this NPRM.

#### **FAA's Determination**

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

#### **Proposed AD Requirements**

This proposed AD would require accomplishing the actions specified in the service information identified previously, except as discussed under "Differences Between this Proposed AD and the Service Information."

### Difference Between This Proposed AD and the Service Information

Tables 7, 8, and 9 in paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014, specify post-modification and post-repair inspections, which may be used in support of compliance with section 121.1109(c)(2) or 129.109(b)(2) of the Federal Aviation Regulations 14 CFR 121.1109(c)(2) or 129.109(b)(2)). However, this NPRM does not propose to require those post-modification and post-repair inspections. This difference has been coordinated with Boeing.

Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014, specifies to contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

# Explanation of "RC (Required for Compliance)" Steps in Service Information

The FAA worked in conjunction with industry, under the Airworthiness **Directive Implementation Aviation** Rulemaking Committee (ARC), to enhance the AD system. One enhancement was a new process for annotating which steps in the service information are required for compliance with an AD. Differentiating these steps from other tasks in the service information is expected to improve an owner's/operator's understanding of crucial AD requirements and help provide consistent judgment in AD compliance. The steps identified as RC (required for compliance) in any service information identified previously have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition.

For service information that contains steps that are labeled as Required for Compliance (RC), the following provisions apply: (1) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD, and an alternative method of compliance (AMOC) is required for any deviations to RC steps, including substeps and identified figures; and (2)

steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

#### **Costs of Compliance**

We estimate that this proposed AD affects 609 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

#### **ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspections	33 work-hours $\times$ \$85 per hour = \$2,805 per inspection cycle.	\$0	\$2,805 per inspection cycle.	\$1,708,245 per inspection cycle.

We estimate the following costs to do any necessary [repairs/modifications] that would be required based on the results of the proposed inspection. We have no way of determining the number

of aircraft that might need these repairs/modifications.

#### **ON-CONDITION COSTS**

Action	Labor cost	Parts cost	Cost per product
Repair and Preventive Modification	63 work-hours × \$85 per hour = \$5,355	\$10,432	Up to \$15,787.

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

#### **Authority for this Rulemaking**

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

#### **Regulatory Findings**

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and

responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

- (1) Is not a "significant regulatory action" under Executive Order 12866,
- (2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979)
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

#### The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

### PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

#### § 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA– 2015–2462; Directorate Identifier 2014 NM–224–AD.

#### (a) Comments Due Date

We must receive comments by September 3, 2015.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to The Boeing Company Model 737–100, –200, –200C, –300, –400, and –500 series airplanes, certificated in any category, as identified in Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014.

#### (d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

#### (e) Unsafe Condition

This AD was prompted by reports of cracked antenna support channels, skin cracking underneath the number 2 VHF antenna, and cracking in the frames attached to the internal support structure. We are issuing this AD to detect and correct skin cracking of the fuselage that could result in separation of the antenna from the airplane and rapid depressurization of the cabin.

#### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

#### (g) Inspection and Follow-on Actions: Group 1

For airplanes identified as Group 1 in Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014: Within 120 days after the effective date of this AD, inspect for cracking at the number 2 VHF antenna location, and do all applicable follow-on actions, using a method approved in accordance with the procedures specified in paragraph (m) of this AD.

#### (h) Inspection and Follow-on Actions: Groups 2 through 6, Configurations 1 through 3

For airplanes identified as Groups 2 through 6, configurations 1 through 3 in Boeing Special Attention Service Bulletin 737-53-1159, Revision 1, dated October 20, 2014: Within 1,250 flight cycles after the effective date of this AD, do an external detailed inspection for cracking of the fuselage skin, as applicable, and do all corrective actions, in accordance with Part 1 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737-53-1159, Revision 1, dated October 20, 2014. Thereafter, at the applicable time specified in paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737-53-1159, Revision 1, dated October 20, 2014, except as required by paragraph (l)(1) of this AD: Do all applicable actions specified in paragraphs (h)(1) through (h)(4) of this AD.

(1) Repeat the Part 1 inspection specified in paragraph (h) of this AD until the accomplishment of paragraphs (k)(1) and (k)(2) of this AD, as applicable.

(2) Inspect for cracking at the number 2 VHF antenna location using internal and external detailed inspections, internal and external high frequency eddy current (HFEC) inspections, and an HFEC open-hole inspection, in accordance with Part 2 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014. Repeat the inspections until the accomplishment of paragraphs (k)(1) and (k)(2) of this AD, as applicable.

(3) Repair any crack found, in accordance with Part 3 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014, except as required by

paragraph (l)(2) of this AD.

(4) Do a preventive modification, in accordance with Part 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737 53 1159, Revision 1, dated October 20, 2014, except as specified in paragraph (l)(2) of this AD. The accomplishment of this preventive modification terminates the inspections required by paragraphs (g), (g)(1), and (h)(2) of this AD.

#### (i) Inspection and Follow-on Actions: Groups 3 through 6, Configuration 4

For airplanes identified as Groups 3 through 6, Configuration 4, in Boeing Special Attention Service Bulletin 737-53-1159, Revision 1, dated October 20, 2014: At the applicable time specified in table 10 of paragraph 1.E., "Compliance," of Boeing Special Attention Service Bulletin 737–53– 1159, Revision 1, dated October 20, 2014; Do an external detailed inspection for cracking at the outer row of fasteners common to the internal repair doubler, and do an internal general visual inspection for cracking on the modified internal support structure of the number 2 VHF antenna, skin, and surrounding stringers, channel, and frames, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737-53-1159, Revision 1, dated October 20, 2014.

(1) If any cracking is found, before further flight, repair using a method approved in accordance with the procedures specified in paragraph (m) of this AD.

(2) If no cracking is found, repeat the inspections at the time specified in table 10 of paragraph 1.E., "Compliance," of Boeing SB 737–53–1159, Revision 1, dated October 20, 2014.

#### (j) Post Repair/Post Modification Inspections

For airplanes identified as Group 2, Configuration 1, and Groups 3 through 6, Configurations 1 through 3, in Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014: The postrepair/post-modification inspections specified in tables 7 through 9 of paragraph 1.E., "Compliance" of Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014, are not required by this AD.

Note 1 to paragraph (j) of this AD: The post-repair/post-modification inspections specified in tables 7 through 9 of paragraph 1.E., "Compliance" of Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014, may be used in support of compliance with section 121.1109(c)(2) or 129.109(b)(2) for the Federal Aviation Regulations (14 CFR 121.1109(c)(2) or 14 CFR 129.109(b)(2)).

#### (k) Terminating Action Provisions

The following describes terminating action for the airplane groups and configurations, as identified in Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014.

(1) For airplanes in Group 2, Configuration 2; and Groups 3 through 6, Configuration 2: Accomplishment of the inspections specified in paragraph (h)(2) of this AD terminates the repetitive inspection requirements of paragraph (h)(1) of this AD.

(2) For airplanes in Group 2, Configuration 1, and Groups 3 through 6, Configuration 1, 2, and 3: Accomplishment of the repair specified in paragraph (h)(3) of this AD terminates the repetitive inspections specified in paragraph (h)(1) and (h)(2) of this AD.

(3) For airplanes in Group 2, Configuration 1; and Groups 3 through 6, Configurations 1 and 3: Accomplishment of the preventive modification specified in paragraph (h)(4) of this AD terminates the initial and repetitive inspections specified in paragraphs (h), (h)(1), and (h)(2) of this AD.

### (l) Exception to Service Bulletin Specifications

(1) Where Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014 compliance is "after the Revision 1 date of this service bulletin," this AD requires compliance within the specified compliance time after the effective date of this AD. Do the inspection, in accordance with the Accomplishment Instructions of the Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014.

(2) Where Boeing Special Attention Service Bulletin 737–53–1159, Revision 1, dated October 20, 2014, specifies to contact Boeing for appropriate action, and specifies that action as "RC" (Required for Compliance): Before further flight, repair the cracking using a method approved in accordance with the procedures specified in paragraph (m) of this AD.

### (m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (n)(2) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/

certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD if it is approved by Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (m)(4)(i) and (m)(4)(ii) apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

#### (n) Related Information

(1) For more information about this AD, contact Wayne Lockett, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6447; fax: 425–917–6590; email: wayne.lockett@faa.gov.

(2) For information on AMOCs, contact Nenita Odesa, Aerospace Engineer, Airframe Branch, ANM-120L, FAA, Los Angeles Aircraft Certification Office (ACO), 3960 Paramount Boulevard, Lakewood, CA 90712-4137; phone: 562-627-5210; fax: 562-627-5234; email: nenita.odesa@faa.gov.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet https://www.myboeingfleet.com. You

may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on July 10, 2015.

#### Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service. [FR Doc. 2015–17688 Filed 7–17–15; 8:45 am] BILLING CODE 4910–13–P

#### DEPARTMENT OF TRANSPORTATION

#### **Federal Aviation Administration**

#### 14 CFR Part 71

[Docket No. FAA-2015-1137; Airspace Docket No. 15-ANM-4]

### Proposed Amendment of Class E Airspace; Portland, OR

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking

(NPRM).

**SUMMARY:** This action proposes to modify Class E surface area airspace designated as an extension to the Class C airspace, and Class E airspace extending upward from 700 feet above the surface at Portland International Airport, Portland, OR. After reviewing the airspace, the FAA found the Portland VHF omnidirectional radio range/distance measuring equipment (VOR/DME) and Laker non-directional beacon (NDB) have been decommissioned, thereby necessitating airspace redesign for the safety and management of Instrument Flight Rules (IFR) operations at the airport. This proposal also would correct the geographic coordinates of the airport. DATES: Comments must be received on

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590; telephone (202) 366-9826. You must identify FAA Docket No. FAA-2015-1137; Airspace Docket No. 15-ANM-4, at the beginning of your comments. You may also submit comments through the Internet at http://www.regulations.gov. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1-800-647-5527), is

or before September 3, 2015.

on the ground floor of the building at the above address.

FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at <a href="http://www.faa.gov/air\_traffic/publications/">http://www.faa.gov/air\_traffic/publications/</a>. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to <a href="http://www.archives.gov/federal\_register/code\_of\_federal-regulations/ibr\_locations.html">http://www.archives.gov/federal\_register/code\_of\_federal-regulations/ibr\_locations.html</a>.

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15. For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC, 20591; telephone: 202–267–8783.

#### FOR FURTHER INFORMATION CONTACT:

Steve Haga, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4563.

#### SUPPLEMENTARY INFORMATION:

#### **Authority for This Rulemaking**

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part, A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class E airspace at Portland International Airport, Portland, OR.

#### **Comments Invited**

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both

docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA–2015–1137; Airspace Docket No. 15–ANM–4." The postcard will be date/time stamped and returned to the commenter.

#### **Availability of NPRMs**

An electronic copy of this document may be downloaded through the Internet at http://www.regulations.gov.
Recently published rulemaking documents can also be accessed through the FAA's Web page at http://www.faa.gov/airports\_airtraffic/air\_traffic/publications/airspace\_amendments/.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the ADDRESSES section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Center, Operations Support Group, 1601 Lind Avenue SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

#### Availability and Summary of Documents Proposed for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014. FAA Order 7400.9Y is publicly available as listed in the ADDRESSES section of this proposed rule. FAA Order 7400.9Y lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

#### The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) Part 71 by modifying Class E airspace designated as an extension to Class C airspace, and Class E airspace extending upward from 700 feet above the surface at Portland International Airport, Portland, OR. A review of the

airspace revealed modification necessary due to the decommissioned Portland VOR/DME and Laker NDB navigation aids. Also, the geographic coordinates of the airport would be amended to coincide with the FAA's aeronautical database.

Class E airspace designated as an extension to Class C airspace would be modified to an area 4.7 miles west and 4 miles east of the 044° bearing from Portland International Airport extending to 18 miles northeast of the airport. The lateral boundary for Class E airspace extending upward from 700 feet above the surface would be defined utilizing latitudinal and longitudinal reference points instead of navigation aids. This would not change the lateral boundaries or operating requirements of the airspace.

Class E airspace designations are published in paragraph 6003 and 6005, respectively, of FAA Order 7400.9Y, dated August 6, 2014, and effective September 15, 2014, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

#### Regulatory Notices and Analyses

The FAA has determined this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation; (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### **Environmental Review**

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

# PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

#### §71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014, is amended as follows:

Paragraph 6003 Class E Airspace Areas Designated as an Extension \* \* \* \* \*

#### ANM OR E3 Portland, OR [Modified]

Portland International Airport, OR (Lat. 45°35′19″ N., long. 122°35′49″ W.)

That airspace extending upward from the surface bounded by a line beginning at lat. 45°40′10″ N., long. 122°37′24″ W.; to lat. 45°41′14″ N., long. 122°37′21″ W.; to lat. 45°51′45″ N., long. 122°21′16″ W.; to lat. 45°45′40″ N., long. 122°13′32″ W.; to lat. 45°35′11″ N., long. 122°28′45″ W.; thence counter-clockwise along the 5-mile radius of Portland International Airport to the point of beginning.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 feet or More Above the Surface of the Earth \* \* \* \* \*

#### ANM OR E5 Portland, OR [Modified]

Portland International Airport, OR (Lat. 45°35′19″ N., long. 22°35′49″ W.) McMinnville, McMinnville Municipal Airport, OR

(Lat. 45°11′40″ N., long. 123°08′10″ W.)

That airspace extending upward from 700 feet above the surface bounded by a line beginning at lat. 45°59′59" N., long. 123°30′04" W.; to lat. 46°00′00" N., long. 122°13′00" W.; thence via an 8.5-mile radius centered at lat. 45°55′07″ N., long. 122°03′02″ W. clockwise to lat. 45°46′39" N., long 122°04′00″ W.; thence via a line south to lat. 45°09′59″ N., long. 122°04′00″ W.; thence to lat. 45°09′59" N., long. 123°02′23" W.; and within a 4.3-mile radius of McMinnville Municipal Airport; and within 2 miles each side of the 215° bearing from McMinnville Municipal Airport to lat. 45°09′59″ N., long. 123°13′21″ W.; to lat. 45°09′59″ N., long. 123°30′04″ W.; thence to the point of beginning; that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat.  $46^{\circ}30'29''$  N., long. 124°06′51" W.; to lat. 46°30′29" N., long.

 $120^{\circ}29'40'' \text{ W.; to lat. } 45^{\circ}42'49'' \text{ N., long.} \\ 121^{\circ}06'03'' \text{ W.; to lat. } 44^{\circ}15'10'' \text{ N., long.} \\ 121^{\circ}18'13'' \text{ W.; to lat. } 44^{\circ}29'59'' \text{ N., long.} \\ 123^{\circ}17'38'' \text{ W.; to lat. } 44^{\circ}29'59'' \text{ N., long.} \\ 124^{\circ}08'036'' \text{ W. to a point 2.7 miles offshore;} \\ \text{thence along a line 2.7 miles offshore to the point of beginning.} \\$ 

Issued in Seattle, Washington, on July 7, 2015.

#### Christopher Ramirez,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2015–17502 Filed 7–17–15; 8:45 am] **BILLING CODE 4910–13–P** 

#### **DEPARTMENT OF TRANSPORTATION**

#### **Federal Aviation Administration**

#### 14 CFR Part 73

[Docket No. FAA-2015-2193; Airspace Docket No. 15-AWP-8]

RIN 2120-AA66

# Proposed Establishment of Restricted Area R–2507W; Chocolate Mountains, CA

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to establish restricted area R–2507W, Chocolate Mountains, CA, to support training activities that involve the use of advanced weapons systems. Proposed R–2507W is needed by the United States Marine Corps (USMC) to enhance training and safety requirements in order to maintain, train, and equip combat-ready military forces.

**DATES:** Comments must be received on or before September 3, 2015.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M– 30, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590-0001; telephone: (202) 366-9826. You must identify FAA Docket No. FAA-2015-2193 and Airspace Docket No. 15-AWP-8, at the beginning of your comments. You may also submit comments through the Internet at www.regulations.gov. Comments on environmental and land use aspects to should be directed to: Kelly Finn, Naval Facilities Engineering Command Southwest, 1220 Pacific Highway, Building 1, Room 323, San Diego, CA 92132; telephone: (619) 532-4452.

#### FOR FURTHER INFORMATION CONTACT:

Jason Stahl, Airspace Policy and Regulations Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267-8783.

#### SUPPLEMENTARY INFORMATION:

#### Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the

agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the restricted area airspace at Chocolate Mountains, CA, to enhance aviation safety and accommodate essential USMC training requirements.

#### Background

The Chocolate Mountain Aerial Gunnery Range (CMAGR), located in Imperial and Riverside Counties, CA is primarily used for live-fire aviation and ground warfare training conducted by USMC and Navy forces. Marine aviation plays a crucial role in the ability of Marine Air-Ground Task Forces (MAGTF) to conduct maneuver warfare. The ultimate goal of Marine aviation is to attain the highest possible combat readiness to support expeditionary maneuver warfare while preserving and conserving Marine forces and equipment. Embedded within combat readiness is the requirement that Marine aviation units maintain the ability to rapidly, effectively, and efficiently deploy a combat-capable aircrew and aircraft on short notice, and maintain the ability to quickly and effectively plan for crises and/or contingency operations. R-2507W would allow Marine aviation to attain and maintain this capability.

Current procedures require the periodic renewal of the CFAs over this area. Because nonparticipating aircraft may transit the CFAs without limitation and without warning, safety of flight concerns often result in lengthy training interruptions and failure to meet training requirements. A higher-level demand for greater throughput of both ground and aviation training in order to support real world operations will likely increase the frequency of these incidents. The USMC considered the

existing R-2507N and the adjacent R-2507S restricted areas in order to meet the expanded training requirements. The existing restricted areas, which are primarily used for aerial ordnance delivery and air strikes, are incompatible with required co-use ground training activities. Alternate location suitability studies were conducted to examine alternatives for the ground training activities. The studies determined that the training capabilities offered in the proposed R-2507W are unique and cannot be replicated elsewhere without significant cost, time, and undue degradation or failure to meet USMC requirements.

#### **Comments Invited**

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA-2015–2193 and Airspace Docket No. 15– AWP–8) and be submitted in triplicate to the Docket Management System (see ADDRESSES section for address and phone number). You may also submit comments through the Internet at www.regulations.gov.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2015-2193 and Airspace Docket No. 15-AWP-8." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

#### Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at www.regulations.gov.

You may review the public docket containing the proposal, any comments received and any final disposition in person at the Dockets Office (see ADDRESSES section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Western Service Center, Federal Aviation Administration, 1601 Lind Ave. SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

#### The Proposal

This proposal would establish new restricted area. R-2507W to accommodate live direct and indirect surface to surface fires associated with established live fire ranges and maneuver areas supporting Naval Special Warfare and Marine Corps ground unit training. This proposed restricted area is required to effectively de-conflict Department of Defense and civilian air traffic from hazards associated with live fire training.

Specific aviation activities and maximum altitudes within the R-2507W would include both live fire and non-live fire aviation training activities such as Basic Ordnance Delivery, Close Air Support, Air-to-Air Gunnery, Laser Ranging and Designating, and Air Strikes. As part of the Marine Corps' training in R-2507, the Marine Corps Air Command and Control organization will develop a battle space management plan. This plan will establish ground fire support and airspace coordination measures in a way that integrates ground and air operations in planning and execution within the MAGTF. Supersonic flight will not be conducted as part of the above aviation training activities.

Surface-to-surface and surface-to-air activities conducted within the R-2507W would include live fire from various small arms, machine guns, antitank weapons, mortars, and hand grenades. Direct fire weapons will be used in this area 6–24 hours per day, no less than 300 days per year. A minimum of 40 percent use of the planned live fire ranges will occur during hours of darkness (from 2200-0700).

Expansion of the current restricted area complex supports an increase in both Marine Corps and Naval aviation and ground training requirements. In addition, the expansion would allow critically required co-use of R–2507W in order to meet those increased training requirements.

#### Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### **Environmental Review**

This proposal will be subjected to an environmental analysis in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures," prior to any FAA final regulatory action.

#### List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

#### The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 73 as follows:

#### PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

#### § 73.25 California (Amended)

■ 2. § 73.25 is amended as follows:

### R-2507W West Chocolate Mountains, CA [New]

Boundaries. Beginning at latitude 33°14′00″ N., longitude 115°22′33″ W.; to latitude 33°13′14″ N., longitude

115°23′17" W.; to latitude 33°13′58" N., longitude 115°24′26" W.; to latitude 33°14′22″ N., longitude 115°25′29″ W.; to latitude 33°15'40" N., longitude 115°27'36" W.; to latitude 33°17'28" N., longitude 115°29′42″ W.; to latitude 33°19′17″ N., longitude 115°32′13″ W.; to latitude 33°21′11" N., longitude 115°34′39" W.; to latitude 33°22′58" N., longitude 115°38'19" W.; to latitude 33°27′26″ N., longitude 115°43′30″ W.; to latitude 33°29'25" N., longitude 115°46′08" W.; to latitude 33°31′09" N., longitude 115°41′12″ W.; to latitude 33°32′50″ N., longitude 115°37′37″ W.: to latitude 33°32'40" N., longitude 115°33′53″ W.; to latitude 33°28′30″ N., longitude 115°42′13″ W.; to latitude 33°23′40″ N., longitude 115°33′23″ W.; to latitude 33°21′30″ N., longitude 115°32′58" W.; to the point of beginning.

Designated altitudes. Surface to FL 230.

Time of designation. Continuous. Controlling agency. FAA, Los Angeles Air Route Traffic Control Center (ARTCC).

Using agency. USMC, Commanding Officer, Marine Corps Air Station (MCAS) Yuma, AZ.

Issued in Washington, DC, on July 14, 2015.

#### Gary Norek,

Manager, Airspace Policy and Regulations Group.

[FR Doc. 2015–17702 Filed 7–17–15; 8:45 am] BILLING CODE 4910–13–P

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R06-OAR-2015-0027; FRL-9930-78-Region-6]

#### Approval and Promulgation of Air Quality Implementation Plans; Texas; Low Reid Vapor Pressure Fuel Regulations

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Texas State Implementation Plan (SIP) related to Low Reid Vapor Pressure (RVP) Fuel Regulations that were submitted by the State of Texas on January 5, 2015. The EPA evaluated the Texas SIP submittal and determined these revisions are consistent with the requirements of the Clean Air Act (Act or CAA). The EPA is approving this action under the federal CAA.

**DATES:** Written comments should be received on or before August 19, 2015.

ADDRESSES: Comments may be mailed to Ms. Mary Stanton, Chief, Air Grants Section (6PD–S), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the ADDRESSES section of the direct final rule located in the rules section of this Federal Register.

# FOR FURTHER INFORMATION CONTACT: Tracie Donaldson, (214) 665–6633, Donaldson.tracie@epa.gov.

SUPPLEMENTARY INFORMATION: In the final rules section of this Federal Register, EPA is approving the State's SIP submittal as a direct rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action no further activity is contemplated. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: July 7, 2015.

#### Ron Curry,

Regional Administrator, Region 6. [FR Doc. 2015–17742 Filed 7–17–15; 8:45 am] BILLING CODE 6560–50–P

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R04-OAR-2015-0133; FRL-9930-86-Region 4]

#### Approval and Promulgation of Implementation Plans; Florida; Combs Oil Company Variance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve a revision to the State Implementation Plan (SIP) submitted by the State of Florida through the Department of Environmental Protection (DEP) on July

31, 2009. The revision grants a variance to the Combs Oil Company, located in Naples, Florida. This source specific revision relieves the Combs Oil Company of the requirement to comply with the Florida rule governing installation and operation of vapor collection and control systems on loading racks at bulk gasoline plants. EPA is proposing approval of Florida's July 31, 2009, SIP revision.

**DATES:** Written comments must be received on or before August 19, 2015. ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2015-0133, by one of the following methods:

- 1. www.regulations.gov: Follow the on-line instructions for submitting comments.
  - 2. Email: R4-ARMS@epa.gov.
  - 3. Fax: (404) 562-9019.
- 4. Mail: "EPA-R04-OAR-2015-0133," Air Regulatory Management Section (formerly Regulatory Development Section), Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960.
- 5. Hand Delivery or Courier: Lynorae Benjamin, Chief, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA-R04-OAR-2015-0133. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through www.regulations.gov or email, information that you consider to be CBI or otherwise protected. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through

www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at http:// www.epa.gov/epahome/dockets.htm.

Docket: All documents in the electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the FOR **FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays. FOR FURTHER INFORMATION CONTACT:

Sean Lakeman, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. The telephone number is (404) 562-9043. Mr. Lakeman can be reached via electronic mail at lakeman.sean@ epa.gov.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

The Florida Rule 62–296.418 requires bulk gasoline plants which began operation on or after August 1, 2007, to install and operate vapor collection and control systems on their loading racks.

The rule became effective on May 9, 2007, and was submitted to EPA as a proposed SIP revision on May 31, 2007. EPA approved the SIP revision on June 1, 2009 (74 FR 26103).

On May 30, 2007, Combs Oil Company submitted a petition for variance from the requirements of Rule 62-296.418(2)(b)2, Florida Administrative Code (F.A.C.), for its new bulk gasoline plant. The company operates an existing bulk gasoline plant in Naples, Florida. The new plant would replace the existing plant and be constructed at a different site in the area. However, between July 2005 and January 2007, the company experienced substantial construction delays beyond its control due to the effects of hurricanes, both in Florida and along the upper Gulf Coast. The company experienced delays in obtaining steel for the office and loading/tank areas as well as the rationing of steel rebar and concrete supplies. Combs Oil Company had invested \$67,053 in equipment and \$40,235 in construction costs for the support structure of the loading rack prior to the DEP's initiation of rule 62-296.418(2)(b)2, requiring a vapor collection and control system on the loading racks of new bulk gasoline plants. However, the company was unable to complete construction and relocation of its plant by August 1, 2007, due to the aforementioned construction delays.

Under Section 120.542 of the Florida Statutes, the DEP may grant a variance when the person subject to a rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means, or when application of a rule would create a substantial hardship or violate principles of fairness. The DEP determined that Combs Oil Company had demonstrated that principles of fairness would be violated because the delays in building and relocating to the new facility, related to hurricanes, were beyond the control of the company. Therefore, the DEP issued an Order Granting Variance to Combs Oil Company on August 20, 2008, relieving the company from the requirements of Rule 62–296.418(2)(b)2., F.A.C., for its proposed new facility.

#### II. Analysis of State Submittal

Section 110(l) of the CAA requires that SIP revisions must not interfere with any applicable requirement concerning attainment and reasonable further progress. Like the facility it is replacing, the new Combs Oil facility is located in Collier County in Southwest Florida. Collier County has never been designated nonattainment for any air

pollutant and, thus, is not subject to any reasonable further progress requirements. Air quality monitoring is currently available in the county for ozone. A comparison of the Collier County data in relation to the National Ambient Air Quality Standards for ozone is indicating that value is well within the compliance level. The ozone design value for 2011–2013 in Collier County is 0.060 parts per million (ppm). The proposed SIP revision involves

emissions of volatile organic compounds (VOC), a precursor to ozone. For fine particulate matter  $(PM_{2.5})$ , County-level nitrogen oxide, volatile organic compound and ammonia emissions were not considered because ambient PM<sub>2.5</sub> concentrations in the southeastern U.S. tend to be impacted most significantly by emissions of direct  $PM_{2.5}$  emissions and  $SO_2$  emissions. As a result of the time involved in the chemical and physical transformations of the precursor emissions, the primary impact of the source cannot be explicitly determined but can be evaluated in terms of its addition to the county and regional emissions from all sources in this area.

The proposed source is currently operating in the county and is simply moving a relatively short distance (1.6 miles) within the same general area. Emissions of VOC from gasoline operations at the relocated source are estimated to be the same as VOC emissions at the existing facility, even when the increased storage capacity at the new location is considered. Specifically, VOC emissions are estimated to be less than 3 tons per year—minor in comparison to the county total of 31,816 tons per year. Since ozone concentration levels are currently well below the ambient air quality standard of 0.075 ppm, and emissions of VOC will not increase as a result of the relocation of this source, EPA has preliminary determined that the variance will not interfere with the area's ability to continue to maintain the ozone standards. Thus, EPA has preliminarily determined that the changes are consistent with the Clean Air Act (CAA or Act).

#### III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule, regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference the "Combs Oil Company Source Specific Variance" order granting variance on August 20, 2008. EPA has made, and will continue to make, these documents generally available

electronically through www.regulations.gov and/or in hard copy at the appropriate EPA office (see the ADDRESSES section of this preamble for more information).

#### IV. Final Action

EPA is proposing to approve a source specific SIP revision submitted by the Florida DEP on July 31, 2009. The revision grants a variance to the Combs Oil Company, located in Naples, Florida. This source specific revision relieves the Combs Oil Company of the requirement to comply with the Florida rule governing installation and operation of vapor collection and control systems on loading racks at bulk gasoline plants. It should be noted that approval of the variance for Combs Oil Company only relieves them from the requirements of Rule 62-296.418(2)(b)2 F.A.C., for its new bulk gasoline plant, it does not relieve them from any requirements established in 40 CFR parts 60 and 63.

### IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. See 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves a state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or

- safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Nitrogen dioxide, Particulate Matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 et seq.

Dated: July 6, 2015.

#### Heather McTeer Toney,

Regional Administrator, Region 4. [FR Doc. 2015–17736 Filed 7–17–15; 8:45 am]

BILLING CODE 6560-50-P

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R04-OAR-2013-0185; FRL-9930-87-Region 4]

Approval and Promulgation of Implementation Plans; Alabama; Infrastructure Requirements for the 2008 Lead National Ambient Air Quality Standards

**AGENCY:** Environmental Protection Agency (EPA).

Agency (EFA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve in part, and disapprove, the November 4, 2011, State Implementation Plan (SIP) submission, provided by the Alabama

Department of Environmental Management (ADEM) for inclusion into the Alabama SIP. This proposal pertains to the Clean Air Act (CAA or the Act) infrastructure requirements for the 2008 Lead national ambient air quality standards (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an "infrastructure" SIP. ADEM certified that the Alabama SIP contains provisions that ensure the 2008 Lead NAAOS is implemented, enforced, and maintained in Alabama. With the exception of provisions pertaining to prevention of significant deterioration (PSD) permitting, which EPA is proposing no action through this notice, and with the exception of the provisions respecting state boards, for which EPA is proposing disapproval, EPA is proposing to approve Alabama's infrastructure SIP submission provided to EPA on November 4, 2011, as satisfying the required infrastructure elements for the 2008 Lead NAAQS.

**DATES:** Written comments must be received on or before August 19, 2015. **ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R04–OAR–2013–0185, by one of the following methods:

- 1. www.regulations.gov: Follow the on-line instructions for submitting comments.
  - 2. Email: R4-ARMS@epa.gov.
  - 3. Fax: (404) 562-9019.
- 4. Mail: "EPA-R04-OAR-2013-0185," Air Regulatory Management Section, (formerly the Regulatory Development Section), Air Planning and Implementation Branch, (formerly the Air Planning Branch) Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960.
- 5. Hand Delivery or Courier: Lynorae Benjamin, Chief, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA-R04-OAR-2013-0185. EPA's policy is that all comments received will be included in the public

docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through www.regulations.gov or email, information that you consider to be CBI or otherwise protected. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at http:// www.epa.gov/epahome/dockets.htm.

Docket: All documents in the electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the FOR **FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Zuri Farngalo, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9152. Mr. Farngalo can be reached via electronic mail at farngalo.zuri@epa.gov.

#### SUPPLEMENTARY INFORMATION:

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- V. Proposed Action
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#### I. Background

On October 5, 1978, EPA promulgated a primary and secondary NAAQS under section 109 of the Act. See 43 FR 46246. Both the primary and secondary standards were set at a level of 1.5 micrograms per cubic meter (µg/m³), measured as Lead in total suspended particulate matter (Pb-TSP), not to be exceeded by the maximum arithmetic mean concentration averaged over a calendar quarter. This standard was based on the 1977 Air Quality Criteria for Lead (USEPA, August 7, 1977). On November 12, 2008 (75 FR 81126), EPA issued a final rule to revise the primary and secondary Lead NAAQS. The revised primary and secondary Lead NAAQS were revised to 0.15 µg/m<sup>3</sup>. By statute, SIPs meeting the requirements of sections 110(a)(1) and (2) are to be submitted by states within three years after promulgation of a new or revised NAAQS. Sections 110(a)(1) and (2) require states to address basic SIP requirements, including emissions inventories, monitoring, and modeling to assure attainment and maintenance of the NAAQS. States were required to submit such SIPs to EPA no later than October 15, 2011, for the 2008 Lead NAAQS.1

<sup>&</sup>lt;sup>1</sup> In these infrastructure SIP submissions states generally certify evidence of compliance with sections 110(a)(1) and (2) of the CAA through a combination of state regulations and statutes, some of which have been incorporated into the federally-approved SIP. In addition, certain federally-approved, non-SIP regulations may also be appropriate for demonstrating compliance with sections 110(a)(1) and (2). Throughout this rulemaking, unless otherwise indicated, the term "ADEM Administrative Code" or "ADEM Admin. Code" refers to regulations that have been approved

Today's action is proposing to in part approve and in part disapprove portions of Alabama's infrastructure SIP submissions for the applicable requirements of the 2008 Lead NAAQS. On March 18, 2015, EPA approved Alabama's November 4, 2011, infrastructure SIP submission regarding the PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of D(i) and (J) for the 2008 Lead NAAQS. See 80 FR 14019. Therefore, EPA is not proposing any action today pertaining to the PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of D(i), and (J) for the 2008 Lead NAAQS. With respect to Alabama's infrastructure SIP submissions related to section 110(a)(2)(E)(ii) requirements respecting the section 128 state board requirements, EPA is proposing to disapprove this element of Alabama's submissions in today's rulemaking. For the aspects of Alabama's submittal proposed for approval today, EPA notes that the Agency is not approving any specific rule, but rather proposing that Alabama's already approved SIP meets certain CAA requirements.

### II. What elements are required under sections 110(a)(1) and (2)?

Section 110(a) of the CAA requires states to submit SIPs to provide for the implementation, maintenance, and enforcement of a new or revised NAAOS within three years following the promulgation of such NAAQS, or within such shorter period as EPA may prescribe. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAQS affects the content of the submission. The contents of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains. In the case of the 2008 Lead NAAQS, states typically have met the basic program elements required in section 110(a)(2) through earlier SIP submissions in connection with the 1978 Lead NAAQS.

Section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for "infrastructure" SIP requirements

into Alabama's federally-approved SIP. The terms "Alabama Code" or "Ala. Code" indicate Alabama's state statutes, which are not a part of the SIP unless otherwise indicated.

related to a newly established or revised NAAQS. As mentioned above, these requirements include SIP infrastructure elements such as modeling, monitoring, and emissions inventories that are designed to assure attainment and maintenance of the NAAOS. The requirements that are the subject of this proposed rulemaking are listed below 2 and in EPA's October 14, 2011, memorandum entitled "Guidance on Infrastructure State Implementation Plan (SIP) Elements Required Under Sections 110(a)(1) and 110(a)(2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS)" (2011 Lead Infrastructure SIP Guidance).

- 110(a)(2)(A): Emission limits and other control measures
- 110(a)(2)(B): Ambient air quality monitoring/data system
- 110(a)(2)(Č): Program for enforcement, PSD, and new source review (NSR)<sup>3</sup>
- 110(a)(2)(D)(i): Interstate transport provisions
- 110(a)(2)(D)(ii): Interstate and International transport provisions
- 110(a)(2)(E): Adequate personnel, funding, and authority
- 110(a)(2)(F): Stationary source monitoring and reporting
- 110(a)(2)(G): Emergency episodes
- 110(a)(2)(H): Future SIP revisions
- 110(a)(2)(I): Nonattainment area plan or plan revision under part D.<sup>4</sup>
- 110(a)(2)(J): Consultation with government officials, public notification, PSD and visibility protection
- 110(a)(2)(K): Air quality modeling/
- 110(a)(2)(L): Permitting fees
- 110(a)(2)(M): Consultation/ participation by affected local entities

# III. What is EPA's approach to the review of infrastructure SIP submissions?

EPA is acting upon the SIP submission from Alabama that

addresses the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the Lead NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions "within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)," and these SIP submissions are to provide for the "implementation, maintenance, and enforcement" of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that "[e]ach such plan" submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as "infrastructure SIP" submissions. Although the term "infrastructure SIP" does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as "nonattainment SIP" or 'attainment plan SIP'' submissions to address the nonattainment planning requirements of part D of title I of the CAA, "regional haze SIP" submissions required by EPA rule to address the visibility protection requirements of CAA section 169A, and nonattainment new source review permit program submissions to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions, and section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.<sup>5</sup> EPA

Continued

 $<sup>^{2}</sup>$  Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) because SIPs incorporating necessary local nonattainment area controls are not due within three years after promulgation of a new or revised NAAQS, but rather due at the time the nonattainment area plan requirements are due pursuant to section 172. These requirements are: (1) Submissions required by section 110(a)(2)(C) to the extent that subsection refers to a permit program as required in part D Title I of the CAA, and (2) submissions required by section 110(a)(2)(I) which pertain to the nonattainment planning requirements of part D, Title I of the CAA. Today's proposed rulemaking does not address infrastructure elements related to section 110(a)(2)(I) or the nonattainment planning requirements of 110(a)(2)(C).

<sup>&</sup>lt;sup>3</sup> This rulemaking only addresses requirements for this element as they relate to attainment areas.

<sup>&</sup>lt;sup>4</sup> As mentioned above, this element is not relevant to today's proposed rulemaking.

<sup>&</sup>lt;sup>5</sup> For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address

therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submissions provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

The following examples of ambiguities illustrate the need for EPA to interpret some section 110(a)(1) and section 110(a)(2) requirements with respect to infrastructure SIP submissions for a given new or revised NAAQS. One example of ambiguity is that section 110(a)(2) requires that "each" SIP submission must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and would create a conflict with the nonattainment provisions in part D of title I of the Act, which specifically address nonattainment SIP requirements.6 Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submissions to address nonattainment area requirements are due. For example, section 172(b) requires EPA to establish a schedule for submission of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and section 107(d)(1)(B) allows up to two years, or in some cases three years, for such designations to be promulgated.7 This ambiguity illustrates that rather than apply all the stated requirements of section 110(a)(2) in a strict literal sense, EPA must determine which provisions of section 110(a)(2) are applicable for a particular infrastructure SIP submission.

Another example of ambiguity within sections 110(a)(1) and 110(a)(2) with respect to infrastructure SIPs pertains to whether states must meet all of the

infrastructure SIP requirements in a single SIP submission, and whether EPA must act upon such SIP submission in a single action. Although section 110(a)(1) directs states to submit "a plan" to meet these requirements, EPA interprets the CAA to allow states to make multiple SIP submissions separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submissions to meet the infrastructure SIP requirements, EPA can elect to act on such submissions either individually or in a larger combined action.8 Similarly, EPA interprets the CAA to allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submission for a given NAAQS without concurrent action on the entire submission. For example. EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submission.9

Ambiguities within sections 110(a)(1) and 110(a)(2) may also arise with respect to infrastructure SIP submission requirements for different NAAQS. Thus, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS. The states' attendant infrastructure SIP submissions for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure SIP submission for purposes of section 110(a)(2)(B) could be very different for different pollutants because the content and scope of a state's infrastructure SIP submission to meet this element might be very different for an entirely new

NAAQS than for a minor revision to an existing NAAQS.<sup>10</sup>

EPA notes that interpretation of section 110(a)(2) is also necessary when EPA reviews other types of SIP submissions required under the CAA. Therefore, as with infrastructure SIP submissions, EPA also has to identify and interpret the relevant elements of section 110(a)(2) that logically apply to these other types of SIP submissions. For example, section 172(c)(7) requires that attainment plan SIP submissions required by part D have to meet the "applicable requirements" of section 110(a)(2). Thus, for example, attainment plan SIP submissions must meet the requirements of section 110(a)(2)(A) regarding enforceable emission limits and control measures and section 110(a)(2)(E)(i) regarding air agency resources and authority. By contrast, it is clear that attainment plan SIP submissions required by part D would not need to meet the portion of section 110(a)(2)(C) that pertains to the PSD program required in part C of title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submission may implicate some elements of section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of section 110(a)(1) and section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of section 110(a)(1) and section 110(a)(2)in the context of acting on a particular SIP submission. In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submissions against the list of elements in section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to

emergencies as well as contingency plans that are triggered in the event of such emergencies.

<sup>&</sup>lt;sup>6</sup> See, e.g., "Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO<sub>x</sub> SIP Call; Final Rule," 70 FR 25162, at 25163–65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

<sup>&</sup>lt;sup>7</sup>EPA notes that this ambiguity within section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submission of certain types of SIP submissions in designated nonattainment areas for various pollutants. Note, e.g., that section 182(a)(1) provides specific dates for submission of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

 $<sup>^{8}\,\</sup>mathrm{See},\,e.g.,\,\mathrm{``Approval}$  and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting," 78 FR 4339 (January 22, 2013) (EPA's final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA's 2008 PM2.5 NSR rule), and "Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Infrastructure and Interstate Transport Requirements for the 2006 PM<sub>2.5</sub> NAAQS," (78 FR 4337) (January 22, 2013) (EPA's final action on the infrastructure SIP for the 2006 PM<sub>2.5</sub> NAAQS).

<sup>&</sup>lt;sup>9</sup> On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other section 110(a)(2) infrastructure SIP elements of Tennessee's December 14, 2007 submittal

 $<sup>^{10}\,\</sup>mathrm{For}$  example, implementation of the 1997 PM<sub>2.5</sub> NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

individual SIP submissions for particular elements. 11 EPA issued the Lead Infrastructure SIP Guidance on October 14, 2011.12 EPA developed this document to provide states with up-todate guidance for the 2008 Lead infrastructure SIPs. Within this guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure SIP submissions. The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). Significantly, EPA interprets sections 110(a)(1) and 110(a)(2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.13

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA

and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of "implementation, maintenance, and enforcement" of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

Finally, EPA believes that its approach with respect to infrastructure SIP requirements is based on a reasonable reading of sections 110(a)(1) and 110(a)(2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a "SIP call" whenever the Agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.14 Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions. 15 Significantly, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not

preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action. 16

#### IV. What is EPA's analysis of how Alabama addressed the elements of sections 110(a)(1) and (2) "infrastructure" provisions?

The Alabama infrastructure submission addresses the provisions of sections 110(a)(1) and (2) as described below.

1. 110(a)(2)(A): Emission limits and other control measures: Several regulations within Alabama's SIP are relevant to air quality control regulations. The regulations described below have been federally approved in the Alabama SIP and include enforceable emission limitations and other control measures. Alabama's infrastructure SIP submission cites provisions of the Administrative Code that provide ADEM with the necessary authority to adopt and enforce air quality controls such as Administrative Codes 335-3-1-.03, "Ambient Air Quality Standards," 335–3–1.05 "Sampling and Testing," 335-3-1-.06 "Compliance Schedule," 335-3-14-.03(1)(g) "Standards for Granting Permits" and 335–3–4–.15 "Secondary Lead Smelters." EPA has made the preliminary determination that the provisions contained in these chapters and Alabama's practices are adequate to protect the 2008 Lead NAAQS in the

In this action, EPA is not proposing to approve or disapprove any existing State provisions with regard to excess emissions during startup, shutdown and malfunction (SSM) of operations at a facility. EPA believes that a number of states have SSM provisions which are contrary to the CAA and existing EPA guidance, "State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup, and Shutdown" (September 20, 1999), and

<sup>&</sup>lt;sup>11</sup>EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

<sup>12 &</sup>quot;Guidance on Infrastructure State Implementation Plan (SIP) Elements Required under Clean Air Act Sections 110(a)(1) and 110(a)(2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS)," Memorandum from Stephen D. Page, October 14, 2001.

<sup>&</sup>lt;sup>13</sup> Although not intended to provide guidance for purposes of infrastructure SIP submissions for the 2008 Lead NAAQS, EPA notes, that following the 2011 Lead Infrastructure SIP Guidance, EPA issued the "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2). Memorandum from Stephen D. Page, September 13, 2013. This 2013 guidance provides recommendations for air agencies' development and the EPA's review of infrastructure SIPs for the 2008 ozone primary and secondary NAAQS, the 2010 primary nitrogen dioxide (NO2) NAAQS, the 2010 primary sulfur dioxide (SO2) NAAQS, and the 2012 primary fine particulate matter (PM<sub>2.5</sub>) NAAQS, as well as infrastructure SIPs for new or revised NAAQS promulgated in the future.

<sup>14</sup> For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See "Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions," 74 FR 21639 (April 18, 2011).

<sup>15</sup> EPA has used this authority to correct errors in past actions on SIP submissions related to PSD programs. See "Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule," 75 FR 82536 (December 30, 2010). EPA has previously used its authority under CAA section 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, e.g., 61 FR 38664 (July 25, 1996) and 62 FR 34641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062 (November 16, 2004) (corrections to California SIP); and 74 FR 57051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

<sup>16</sup> See, e.g., EPA's disapproval of a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, e.g., 75 FR 42342 at 42344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4540 (Jan. 26, 2011) (final disapproval of such provisions).

the Agency is addressing such state regulations in a separate action. <sup>17</sup> In the meantime, EPA encourages any state having a deficient SSM provision to take steps to correct it as soon as possible.

Additionally, in this action, EPA is not proposing to approve or disapprove any existing State rules with regard to director's discretion or variance provisions. EPA believes that a number of states have such provisions which are contrary to the CAA and existing EPA guidance (52 FR 45109 (November 24, 1987)), and the Agency plans to take action in the future to address such state regulations. In the meantime, EPA encourages any state having a director's discretion or variance provision which is contrary to the CAA and EPA guidance to take steps to correct the deficiency as soon as possible.

2. 110(a)(2)(B) Ambient air quality monitoring/data system: SIPs are required to provide for the establishment and operation of ambient air quality monitors; the compilation and analysis of ambient air quality data; and the submission of these data to EPA upon request. ADEM Administrative Code, 335–3–1–.03 "Ambient Air Quality Standards," and 335–3–1–.04 "Monitoring Records and Reporting," along with the Alabama Network Description and Ambient Air Network Monitoring Plan, provide for an ambient air quality monitoring system in the State. Annually, States develop and submit to EPA for approval statewide ambient monitoring network plans consistent with the requirements of 40 CFR parts 50, 53, and 58. The annual network plan involves an evaluation of any proposed changes to the monitoring network, includes the annual ambient monitoring network design plan and a certified evaluation of the agency's ambient monitors and auxiliary support equipment.<sup>18</sup> The latest monitoring network plan for Alabama was submitted on July 17, 2014, and on March 6, 2015, EPA approved this plan. Alabama's approved monitoring network plan can be accessed at www.regulations.gov using Docket ID No. EPA-R04-OAR-2013-0185. EPA

has made the preliminary determination that Alabama's SIP and practices are adequate for the ambient air quality monitoring and data system related to the 2008 Lead NAAQS.

3. 110(a)(2)(C) Program for enforcement, PSD, and NSR: This element consists of three sub-elements; enforcement, state-wide regulation of new and modified minor sources and minor modifications of major sources; and preconstruction permitting of major sources and major modifications in areas designated attainment or unclassifiable for the subject NAAQS as required by CAA title I part C (i.e., the major source PSD program). To meet these obligations, Alabama cited ADEM Administrative Codes 335-3-14-.01 "General Provisions," 335-3-14-.02 "Permit Procedure," 335-3-14-.03 "Standards for Granting Permits," 335-3-14.04 "Prevention of Significant Deterioration in Permitting," and 335-3-14-.05 "Air Permits Authorizing Construction in or Near Nonattainment Areas" of Alabama's SIP. ADEM is able to regulate sources of lead through these above cited provisions of Alabama's SIP. In this action, EPA is only proposing to approve the enforcement and the regulation of new minor sources and minor modifications aspects of Alabama's section 110(a)(2)(C) infrastructure SIP submission.

Enforcement: ADEM's abovedescribed, SIP-approved regulations meet the requirements for enforcement of lead emission limits and control measures and construction permitting for new or modified stationary sources.

Preconstruction PSD Permitting for Major Sources: With respect to Alabama's November 4, 2011 infrastructure SIP submission related to the preconstruction PSD permitting requirements for major sources of section 110(a)(2)(C), EPA took final action to approve this provision for the 2008 Lead NAAQS on March 18, 2015. See 80 FR 14019.

Regulation of minor sources and modifications: Section 110(a)(2)(C) also requires the SIP to include provisions that govern a minor source preconstruction program that regulates emissions of the 2008 Lead NAAQS. ADEM Administrative Code 335–3–14–.03 "Standards for Granting Permits" governs the preconstruction permitting of modifications and construction of minor stationary sources in the State.

EPA has made the preliminary determination that Alabama's SIP and practices are adequate for program enforcement of control measures and regulation of minor sources and modifications related to the 2008 Lead NAAQS.

4. 110(a)(2)(D)(i) Interstate transport provisions: Section 110(a)(2)(D)(i) has two components; 110(a)(2)(D)(i)(I) and 110(a)(2)(D)(i)(II). Each of these components have two subparts resulting in four distinct components, commonly referred to as "prongs," that must be addressed in infrastructure SIP submissions. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), are provisions that prohibit any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state ("prong 1"), and interfering with maintenance of the NAAQS in another state ("prong 2"). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), are provisions that prohibit emissions activity in one state interfering with measures required to prevent significant deterioration of air quality in another state ("prong 3"), or to protect visibility in another state ("prong 4"). Section 110(a)(2)(D)(ii) requires SIPs to include provisions insuring compliance with sections 115 and 126 of the Act, relating to interstate and international pollution abatement.

110(a)(2)(D)(i)(I)—prongs 1 and 2: Section 110(a)(2)(D)(i) requires infrastructure SIP submissions to include provisions prohibiting any source or other type of emissions activity in one state from contributing significantly to nonattainment, or interfering with maintenance, of the NAAQS in another state. The physical properties of lead prevent lead emissions from experiencing that same travel or formation phenomena as PM<sub>2.5</sub> and ozone for interstate transport as outlined in prongs 1 and 2. More specifically, there is a sharp decrease in the lead concentrations, at least in the coarse fraction, as the distance from a lead source increases. EPA believes that the requirements of prongs 1 and 2 can be satisfied through a state's assessment as to whether a lead source located within its State in close proximity to a state border has emissions that contribute significantly to the nonattainment or interfere with maintenance of the NAAQS in the neighboring state. For example, EPA's experience with the initial Lead designations suggest that sources that emit less than 0.5 tpy or are located more than two miles from the state border generally appear unlikely to contribute significantly to the nonattainment in another state. Alabama has one lead source that has emissions of lead over 0.5 tons per year (tpy), but because the source is located well beyond two miles from the State

<sup>17</sup> On May 22, 2015, the EPA Administrator signed a final action entitled, "State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunction." The prepublication version of this rule is available at http://www.epa.gov/airquality/urbanair/sipstatus/emissions.html.

<sup>&</sup>lt;sup>18</sup>On occasion, proposed changes to the monitoring network are evaluated outside of the network plan approval process in accordance with 40 CFR part 58.

border,<sup>19</sup> EPA believes it is unlikely to contribute significantly to the nonattainment or interfere with maintenance of the NAAQS in another state. Therefore, EPA has made the preliminary determination that Alabama's SIP meets the requirements of section 110(a)(2)(D)(i)(I).

110(a)(2)(D)(i)(II)—prong 3: With respect to Alabama's infrastructure SIP submission related to the interstate transport requirements for PSD of prong 3 of section 110(a)(2)(D)(i), EPA took final action to approve Alabama's November 4, 2011 infrastructure SIP submission for the 2008 Lead NAAQS on March 18, 2015. See 80 FR 14019.

110(a)(2)(D)(i)(II)—prong 4: With regard to section 110(a)(2)(D)(i)(II), the visibility sub-element, referred to as prong 4, significant visibility impacts from stationary source lead emissions are expected to be limited to short distances from the source. Lead stationary sources in Alabama are located distances from Class I areas such that visibility impacts are negligible. The 2011 Lead Infrastructure SIP Guidance notes that the lead constituent of PM would likely not travel far enough to affect Class 1 areas and that the visibility provisions of the CAA do not directly regulate lead. Accordingly, EPA has preliminarily determined that the Alabama SIP meets the relevant visibility requirements of prong 4 of section 110(a)(2)(D)(i).

5. 110(a)(2)(D)(ii) Interstate and international transport provisions: Section 110(a)(2)(D)(ii) requires SIPs to include provisions insuring compliance with sections 115 and 126 of the Act, relating to interstate and international pollution abatement. ADEM Admin. Code 335–3–14–.04—Prevention of Significant Deterioration in Permitting describes how Alabama notifies neighboring states of potential emission impacts from new or modified sources applying for PSD permits. This regulation requires ADEM to provide an opportunity for a public hearing to the public, which includes State or local air pollution control agencies, "whose lands may be affected by emissions from the source or modification" in Alabama. Additionally, Alabama does not have any pending obligation under sections 115 and 126 of the CAA. Accordingly, EPA has made the preliminary determination that Alabama's SIP and practices are adequate for insuring compliance with the applicable requirements relating to interstate and

international pollution abatement for the 2008 Lead NAAQS.

6. 110(a)(2)(E) Adequate personnel, funding, and authority: Section 110(a)(2)(E) requires that each implementation plan provide (i) necessary assurances that the State will have adequate personnel, funding, and authority under state law to carry out its implementation plan, (ii) that the State comply with the requirements respecting State Boards pursuant to section 128 of the Act, and (iii) necessary assurances that, where the State has relied on a local or regional government, agency, or instrumentality for the implementation of any plan provision, the State has responsibility for ensuring adequate implementation of such plan provisions. EPA is proposing to approve Alabama's SIP as meeting the requirements of sections 110(a)(2)(E)(i) and 110(2)(E)(iii) but disapprove for element 110(2)(E)(ii). EPA's rationale for today's proposals respecting each section of 110(a)(2)(E) is described in turn below.

To satisfy the requirements of section 110(a)(2)(E)(i) and (iii), ADEM's infrastructure SIP submission describes Alabama Code section 22-28-11, which authorizes ADEM to adopt emission requirements though regulations that are necessary to prevent, abate, or control air pollution. Also, Alabama Code section 22-28-9 authorizes the Department to employ necessary staff to carry out responsibilities. The funding requirements are met through the 105 grants and the title V fee process. As further evidence of the adequacy of ADEM's resources, EPA submitted a letter to Alabama on April 24, 2014, outlining 105 grant commitments and the current status of these commitments for fiscal year 2014. The letter EPA submitted to Alabama can be accessed at www.regulations.gov using Docket ID No. EPA-R04-OAR-2013-0185. Annually, states update these grant commitments based on current SIP requirements, air quality planning, and applicable requirements related to the NAAQS. Alabama satisfactorily met all commitments agreed to in the Air Planning Agreement for fiscal year 2014, therefore Alabama's grants were finalized. EPA has made the preliminary determination that Alabama has adequate resources for implementation of the 2008 Lead NAAQS.

To satisfy the requirements of section 110(a)(2)(E)(ii), states must comply with the requirements respecting State Boards pursuant to section 128 of the Act. Section 110(a)(2)(E)(ii) requires that the state comply with section 128 of the CAA. Section 128 requires that the SIP contain provisions that provide: (1) The

majority of members of the state board or body which approves permits or enforcement orders represent the public interest and do not derive any significant portion of their income from persons subject to permitting or enforcement orders under the CAA; and (2) any potential conflicts of interest by such board or body, or the head of an executive agency with similar powers be adequately disclosed. After reviewing Alabama's SIP, EPA has made the preliminary determination that the State's implementation plan does not contain provisions to comply with section 128 of the Act, and thus Alabama's November 4, 2011, infrastructure SIP submission does not meet the requirements of the Act. While Alabama has state statutes that may address, in whole or in part, requirements related to state boards at the state level, these provisions are not included in the SIP as required by the CAA. Based on an evaluation of the federally-approved Alabama SIP, EPA is proposing to disapprove Alabama's infrastructure SIP submission as meeting the requirements of 110(a)(2)(E)(ii) of the CAA for the 2008 Lead NAAQS. The submitted provisions which purport to address 110(a)(2)(E)(ii) are severable from the other portions of ADEM's infrastructure SIP submission, therefore, EPA is proposing to disapprove those provisions which relate only to sub-element 110(a)(2)(E)(ii).

7. 110(a)(2)(F) Stationary source monitoring system: ADEM's infrastructure SIP submission describes the establishment of requirements for compliance testing by emissions sampling and analysis, and for emissions and operation monitoring to ensure the quality of data in the State. The Alabama infrastructure SIP submission also describes how the major source and minor source emission inventory programs collect emission data throughout the State and ensure the quality of such data. Alabama meets these requirements through ADEM Admin. Codes 335-3-1-.04 "Monitoring, Records, and Reporting," and 335-3-12 "Continuous Monitoring Requirements for Existing Sources." ADEM Admin. Code 335-3-1-.04, details how sources are required as appropriate to establish and maintain records; make reports; install, use, and maintain such monitoring equipment or methods and provide periodic emission reports as the regulation requires. These reports and records are required to be compiled, and submitted on forms furnished by the State. Additionally, ADEM Admin. Code 335-3-12-.02

<sup>&</sup>lt;sup>19</sup>There is one facility in Alabama that has Lead emissions greater than 0.5 tpy. The facility is Sanders Lead Co, Inc., which is located at 100 Sanders Rd Troy, AL 36079. This location is about 45 miles from the Georgia border.

requires owners and operators of emissions sources to "install, calibrate, operate and maintain all monitoring equipment necessary for continuously monitoring the pollutants." 20 ADEM Admin. Code 335-3-1-.13 "Credible Evidence," makes allowances for owners and/or operators to utilize "any credible evidence or information relevant" to demonstrate compliance with applicable requirements if the appropriate performance or compliance test had been performed, for the purpose of submitting compliance certification and can be used to establish whether or not an owner or operator has violated or is in violation of any rule or standard. Accordingly, EPA is unaware of any provision preventing the use of credible evidence in the Alabama SIP.

Additionally, Alabama is required to submit emissions data to EPA for purposes of the National Emissions Inventory (NEI). The NEI is EPA's central repository for air emissions data. EPA published the Air Emissions Reporting Rule (AERR) on December 5, 2008, which modified the requirements for collecting and reporting air emissions data (73 FR 76539). The AERR shortened the time states had to report emissions data from 17 to 12 months, giving states one calendar year to submit emissions data. All states are required to submit a comprehensive emissions inventory every three years and report emissions for certain larger sources annually through EPA's online Emissions Inventory System. States report emissions data for the six criteria pollutants and their associated precursors—nitrogen oxides, sulfur dioxide, ammonia, Lead, carbon monoxide, particulate matter, and volatile organic compounds. Many states also voluntarily report emissions of hazardous air pollutants. Alabama made its latest update to the 2013 NEI on January 13, 2015. EPA compiles the emissions data, supplementing it where necessary, and releases it to the general public through the Web site http:// www.epa.gov/ttn/chief/ eiinformation.html. EPA has made the preliminary determination that Alabama's SIP and practices are adequate for the stationary source

monitoring systems related to the 2008 Lead NAAOS.

8. 110(a)(2)(G) Emergency episodes: This section of the CAA requires that states demonstrate authority comparable with section 303 of the CAA and adequate contingency plans to implement such authority. ADEM Admin. Code 335–3–2 "Air Pollution Emergency" provides for the identification of air pollution emergency episodes, episode criteria, and emissions reduction plans. Alabama's compliance with section 303 of the CAA and adequate contingency plans to implement such authority is also met by Ala. Code section 22-28-21 "Air Pollution Emergencies." Ala. Code section 22-28-21 provides ADEM the authority to order the "person or persons responsible for the operation or operations of one or more air contaminants sources" causing "imminent danger to human health or safety in question to reduce or discontinue emissions immediately." The order triggers a hearing no later than 24-hours after issuance before the **Environmental Management** Commission which can affirm, modify or set aside the Director's order. Additionally, the Governor can, by proclamation, declare, as to all or any part of said area, that an air pollution emergency exists and exercise certain powers in whole or in part, by the issuance of an order or orders to protect the public health. EPA has made the preliminary determination that Alabama's SIP, state laws and practices are adequate to satisfy the infrastructure SIP obligations for emergency powers related to the 2008 Lead NAAQS.

9. 110(a)(2)(H) Future SIP revisions: As previously discussed, ADEM is responsible for adopting air quality rules and revising SIPs as needed to attain or maintain the NAAQS. Alabama has the ability and authority to respond to calls for SIP revisions, and has provided a number of SIP revisions over the years for implementation of the NAAQS. These requirements are met through ADEM Administrative Codes 335-1-1-.03 "Organization and Duties of the Commission," 21 which provides ADEM with the authority to establish, adopt, promulgate, modify, repeal and suspend rules, regulations, or environmental standards which may be applicable to Alabama or "any of its geographic parts" and 335–3–1–.03 "Ambient Air Quality Standards," which provides ADEM the authority to amend, revise, and incorporate the NAAQS into its SIP. Alabama currently

has one area designated nonattainment for the 2008 Lead NAAQS located in Troy, Alabama related to the Sanders Lead Company. ADEM submitted an attainment demonstration for this area on November 9, 2012. EPA approved this attainment demonstration on January 28, 2014. See 79 FR 4407. Accordingly, EPA has made the preliminary determination that Alabama's SIP and practices adequately demonstrate a commitment to provide future SIP revisions related to the 2008 Lead NAAQS, when necessary.

10. 110(a)(2)(J) Consultation with government officials, public notification, PSD, and visibility protection: EPA is proposing to approve Alabama's infrastructure SIP submission for the 2008 Lead NAAQS with respect to the general requirement in section 110(a)(2)(J) to include a program in the SIP that provides for meeting the applicable consultation requirements of section 121, the public notification requirements of section 127; and visibility protection requirements of part C of the Act. With respect to Alabama's infrastructure SIP submission related to the preconstruction PSD permitting requirements of section  $110(a)(2)(\bar{J})$ , EPA took final action to approve Alabama's November 4, 2011 2008 Lead NAAQS infrastructure SIP for these requirements on March 18, 2015. See 80 FR 14019. EPA's rationale for its proposed action regarding applicable consultation requirements of section 121, the public notification requirements of section 127, and visibility protection requirements is described below.

Consultation with government officials (121 consultation): Section 110(a)(2)(J) of the CAA requires states to provide a process for consultation with local governments, designated organizations and federal land managers (FLMs) carrying out NAAQS implementation requirements pursuant to section 121 relative to consultation. ADEM Admin. Code 335-3-1-.03 "Ambient Air Quality Standards," as well as its Regional Haze Implementation Plan (which allows for continued consultation with appropriate state, local, and tribal air pollution control agencies as well as the corresponding FLMs), provide for consultation with government officials whose jurisdictions might be affected by SIP development activities. Specifically, Alabama adopted state-wide consultation procedures for the implementation of transportation conformity which includes the development of mobile inventories for SIP development. These consultation procedures were developed in

<sup>&</sup>lt;sup>20</sup> ADEM Admin. Code 335–3–12–.02 establishes that data reporting requirements for sources required to conduct continuous monitoring in the state should comply with data reporting requirements set forth at 40 CFR part 51, Appendix P. Section 40 CFR part 51, Appendix P includes that the averaging period used for data reporting should be established by the state to correspond to the averaging period specified in the emission test method used to determine compliance with an emission standard for the pollutant/source category in question.

 $<sup>^{21}</sup>$  This regulation has not been incorporated into the federally-approved SIP.

coordination with the transportation partners in the State and are consistent with the approaches used for development of mobile inventories for SIPs. Required partners covered by Alabama's consultation procedures include federal, state and local transportation and air quality agency officials. EPA has made the preliminary determination that Alabama's SIP and practices adequately demonstrate consultation with government officials related to the 2008 Lead NAAQS when necessary.

Public notification (127 public notification): To meet the public notification requirements of section 110(a)(2)(J), ADEM cites Alabama Code § 22–28–21 "Air Pollution Emergencies" and ADEM Administrative Code 335-3-14-.01(7) "Public Participation," which requires that ADEM notify the public of any air pollution alert, warning, or emergency. The ADEM Web site also sites air quality summary data and air quality index reports. Alabama maintains a public Web site on which daily air quality index forecasts and summary data are posted. This Web site can be accessed at: http:// adem.alabama.gov/programs/air/ airquality.cnt. EPA has made the preliminary determination that Alabama's SIP and practices adequately demonstrate the State's ability to provide public notification related to the 2008 Lead NAAOS when necessary. Accordingly, EPA is proposing to approve Alabama's infrastructure SIP submission with respect to section 110(a)(2)(J) public notification.

*Visibility Protection:* The 2011 Lead Infrastructure SIP Guidance notes that the lead constituent of PM would likely not travel far enough to affect Class I areas and that the visibility provisions of the CAA do not directly regulate lead. EPA recognizes that states are subject to visibility protection and regional haze program requirements under Part C of the Act (which includes sections 169A and 169B). However, in the event of the establishment of a new primary NAAQS, the visibility protection and regional haze program requirements under part C of the CAA do not change. EPA thus does not expect states to address visibility for this element in Lead infrastructure submittals. Thus, EPA concludes there are no new applicable visibility protection obligations under section 110(a)(2)(J) as a result of the 2008 Lead NAAQS. Accordingly, EPA is proposing to approve section 110(a)(2)(J) of ADEM's infrastructure SIP submission with respect to visibility.

ÉPA has made the preliminary determination that Alabama's SIP and

practices adequately demonstrate the State's ability to meet the general requirement in section 110(a)(2)(J) to include a program in the SIP that provides for meeting the applicable consultation requirements of section 121, the public notification requirements of section 127 and visibility protection associated with regional haze. EPA has also preliminarily determined that it is appropriate approve the State's Lead infrastructure SIP submission with respect to the visibility aspects of section 110(a)(2)(J). EPA is making no determinations with respect the PSD requirements of section 110(a)(2)(J), which will be addressed in a different notice.

11. 110(a)(2)(K) Air quality modeling/ data: Section 110(a)(2)(K) of the CAA requires that SIPs provide for performing air quality modeling so that effects on air quality of emissions from NAAQS pollutants can be predicted and submission of such data to the USEPA can be made. ADEM Administrative Code 335-3-1-.04 "Monitoring Records and Reporting" and 335-3-14-.04 "Prevention of Significant Deterioration Permitting" which incorporates 40 CFR part 51, Appendix W "Guideline on Air Quality Models," demonstrate that Alabama has the authority to provide relevant data for the purpose of predicting the effect on ambient air quality of the 2008 Lead NAAOS. Additionally, Alabama supports a regional effort to coordinate the development of emissions inventories and conduct regional modeling for several NAAQS, including the 2008 Lead NAAQS, for the southeastern states. Taken as a whole, Alabama's air quality regulations and practices demonstrate that ADEM has the authority to provide relevant data for the purpose of predicting the effect on ambient air quality of the Lead NAAQS. EPA has made the preliminary determination that Alabama's SIP and practices adequately demonstrate the State's ability to provide for air quality and modeling, along with analysis of the associated data, related to the 2008 Lead NAAQS when necessary.

12. 110(a)(2)(L) Permitting fees: This section requires the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under the CAA, a fee sufficient to cover (i) the reasonable costs of reviewing and acting upon any application for such a permit, and (ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other

costs associated with any enforcement action), until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under title V. To satisfy these requirements, ADEM's infrastructure SIP submission cites ADEM Admin. Code 335-1-6 "Application Fees," 22 which are State regulations authorized by legislation. Also, ADEM has an approved Title V program with a fee structure established in ADEM Admin. Code 335-1-7 "Air Division Operating Permit Fees." 23 The Title V fees cover the reasonable cost of implementation and enforcement of PSD and NNSR permits after they have been issued. EPA has made the preliminary determination that Alabama's SIP and practices adequately provide for permitting fees related to the Lead NAAQS, when necessary.

12. 110(a)(2)(M) Consultation/ participation by affected local entities: This element requires states to provide for consultation and participation in SIP development by local political subdivisions affected by the SIP. Alabama Administrative Code 335-3-14-.01(17) "Public Participation," 335-3-14-.04(6) "Public Participation," and 335-3-14-.05(13) "Public Participation, "of the Alabama SIP requires that ADEM notify the public of an application, preliminary determination, the activity or activities involved in the permit action, any emissions change associated with any permit modification, and the opportunity for comment prior to making a final permitting decision. ADEM worked closely with local political subdivisions during the development of its Transportation Conformity SIP and Regional Haze Implementation Plan. Required partners covered by Alabama's consultation procedures include federal, state and local transportation and air quality agency officials. The state and local transportation agency officials are most directly impacted by transportation conformity requirements and are required to provide public involvement for their activities including the analysis demonstrating how they meet transportation conformity requirements. Alabama has worked with the FLMs as a requirement of its regional haze rule. EPA has made the preliminary determination that Alabama's SIP and practices adequately demonstrate consultation with affected

 $<sup>^{\</sup>rm 22}\,\rm This$  regulation has not been incorporated into the federally-approved SIP.

<sup>&</sup>lt;sup>23</sup> Title V program regulations are federally approved but not incorporated into the federally-approved SIP.

local entities related to the 2008 Lead NAAQS when necessary.

#### V. Proposed Action

With the exception of the PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of (D)(i) and (J), and the state board requirements of section 110(a)(2)(E)(ii), EPA is proposing to approve that ADEM's infrastructure SIP submission, submitted November 4, 2011, for the 2008 Lead NAAQS meets the above described infrastructure SIP requirements. EPA is proposing to disapprove section 110(a)(2)(E)(ii) of Alabama's infrastructure submission because the State's implementation plan does not contain provisions to comply with section 128 of the Act, and thus Alabama's November 4, 2011, infrastructure SIP submission does not meet the requirements of the Act. This proposed approval in part and disapproval in part, however, does not include the PSD permitting requirements for major sources of section 110(a)(2)(C), prong 3 of (D)(i) and (J) because the Agency has taken final action on these requirements for 2008 Lead NAAQS for Alabama in a

separate rulemaking. Under section 179(a) of the CAA, final disapproval of a submittal that addresses a requirement of a CAA Part D Plan or is required in response to a finding of substantial inadequacy as described in CAA section 110(k)(5) (SIP call) starts a sanctions clock. The portion of section 110(a)(2)(E)(ii) provisions (the provisions being proposed for disapproval in today's notice) were not submitted to meet requirements for Part D or a SIP call, and therefore, if EPA takes final action to disapprove this submittal, no sanctions will be triggered. However, if this disapproval action is finalized, that final action will trigger the requirement under section 110(c) that EPA promulgate a federal implementation plan (FIP) no later than 2 years from the date of the disapproval unless the State corrects the deficiency, and EPA approves the plan or plan revision before EPA promulgates such FIP.

#### VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves state law as

meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Lead, and Recordkeeping requirements.

Authority: 42 U.S.C. 7401 et seq.

Dated: July 6, 2015.

#### Heather McTeer Toney,

Regional Administrator, Region 4. [FR Doc. 2015–17733 Filed 7–17–15; 8:45 am]

BILLING CODE 6560-50-P

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R04-OAR-2013-0163; FRL-9930-75-Region 4]

#### Approval and Promulgation of Implementation Plans; Mississippi: Miscellaneous Changes

AGENCY: Environmental Protection

Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve portions of a State Implementation Plan (SIP) revision submitted by the Mississippi Department of Environmental Quality (MDEQ), to EPA on July 25, 2010. The SIP revision includes multiple changes to Mississippi's SIP to add definitions in accordance with federal regulations and to implement clarifying language. EPA is not proposing to take action on the aspects of the SIP revision related to the Clean Air Interstate Rule (CAIR) or hazardous air pollutants at this time. **DATES:** Written comments must be received on or before August 19, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2013-0163, by one of the following methods:

- 1. www.regulations.gov: Follow the on-line instructions for submitting comments.
  - $2.\ Email: R4\text{-}ARMS@epa.gov.$
  - 3. Fax: (404) 562-9019.
- 4. Mail: "EPA-R04-OAR-2013-0163," Air Regulatory Management Section (formerly Regulatory Development Section), Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960.
- 5. Hand Delivery or Courier: Lynorae Benjamin, Chief, Air Regulatory Management Section (formerly Regulatory Development Section), Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official

hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA-R04-OAR-2013-0163. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through www.regulations.gov or email, information that you consider to be CBI or otherwise protected. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at http:// www.epa.gov/epahome/dockets.htm.

Docket: All documents in the electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information may not be publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the FOR

**FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

#### FOR FURTHER INFORMATION CONTACT:

Sean Lakeman, Air Regulatory
Management Section, Air Planning and
Implementation Branch, Air, Pesticides
and Toxics Management Division, U.S.
Environmental Protection Agency,
Region 4, 61 Forsyth Street SW.,
Atlanta, Georgia 30303–8960. Mr.
Lakeman can be reached by phone at
(404) 562–9043 or via electronic mail at
lakeman.sean@epa.gov.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

On June 25, 2010, MDEQ submitted a SIP revision to EPA for approval into the Mississippi SIP. MDEQ's July 25, 2010. SIP revision includes multiple changes to Mississippi's air pollution control regulation APC-S-1, entitled 'Air Emission Regulations for the Prevention, Abatement, and Control of Air Contaminants," to add and amend definitions in accordance with federal regulations and to implement clarifying language. Specifically, these changes include amendments to Section 2-"Definitions" and Section 3—"Specific Criteria for Sources of Particulate Matter." With the exception of the changes in Section 8 related to hazardous air pollutants and the changes in Section 14 related to Mississippi's CAIR provisions, EPA is proposing to approve Mississippi's July 25, 2010, SIP revision, which became state effective on February 6, 2009.1 EPA will consider action on Mississippi's changes to its CAIR provisions and its hazardous air pollutants provisions in a separate action.

## II. Mississippi's July 25, 2010, SIP Revision

A. Changes to APC-S-1, Section 2— "Definitions"

#### 1. "Air Cleaning Device"

Mississippi is amending the definition of "Air Cleaning Device" by adding language to clarify that the term "air pollution control device" is synonymous with the term "air cleaning device." The definition of "air cleaning device" includes "[a]ny method, process or equipment which removes, reduces or renders less noxious air contaminants discharged into the atmosphere." Mississippi's July 25, 2010, SIP revision, simply clarifies that the term "air pollution control device" has the same definition as "air cleaning device" by adding a phrase noting that these two terms are "synonymous." Mississippi chose to link the two terms rather than provide a separate definition entry for "air pollution control device." Mississippi is making this change to provide clarity to the regulated community regarding the definition for the term "air pollution control device."

#### 2. "Ozone Action Day"

Mississippi's July 25, 2010, SIP submission amends the definition for "Ozone Action Day" by changing the dates from April 1 and September 30 to March 1 and October 30, respectively, to align with the time period for ozone monitoring in Mississippi as specified in 40 CFR part 58. See table in 40 CFR part 58 entitled, "Table D–3 of Appendix D to Part 58—Ozone Monitoring Season by State."

#### 3. "PM<sub>2.5</sub>"

Mississippi added a definition of " $PM_{2.5}$ " as "[p]articulate matter with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers as measured by a reference method based on appendix L of 40 CFR part 50 and designated in accordance with 40 CFR part 53 or by an equivalent method designated in accordance with 40 CFR part 53." This definition is consistent with EPA's definition codified at 40 CFR part 53 as well as the agency's longstanding characterization of fine particular matter. This change, if approved, will result in a renumbering of definitions at APC–S–1.

#### 4. "PM<sub>2.5</sub> emissions"

Mississippi added a definition of "PM<sub>2.5</sub> emissions" as "[f]inely divided solid or liquid material, with an aerodynamic diameter less than or equal to a nominal 2.5 micrometers, emitted to the ambient air as measured by an applicable EPA Test Method, an equivalent or alternative method specified by EPA, or by a test method specified in the approved State Implementation Plan." This definition is consistent with EPA's definition for "direct PM<sub>2.5</sub> emissions"  $^2$  except that

Continued

¹ MDEQ's submission includes a revision to APC–S–1, Section 8—"Provisions for Hazardous Air Pollutants" that updates the incorporate by reference date to October 3, 2008, for relevant federal regulations related to National Emission Standard for Hazardous Air Pollutants (NESHAPS) and the Clean Air Mercury Rule (CAMR). However, EPA has not incorporated APC–S–1, Section 8 into the Mississippi SIP, and therefore, EPA is not proposing to approve these changes related to NESHAPS and CAMR into the SIP.

 $<sup>^2</sup>$  Under the federal definition, "direct PM $_{2.5}$  emissions" means "solid particles emitted directly from an air emissions source or activity, or gaseous emissions or liquid droplets from an air emissions

the State's definition does not include a condensable PM<sub>2.5</sub> component.<sup>3</sup> However, EPA considers this definition acceptable because there are currently no PM<sub>2.5</sub> nonattainment areas in Mississippi and because the State's prevention of significant deterioration (PSD) program at APC–S–5 requires sources to consider the condensable portion of PM<sub>2.5</sub> emissions when determining PSD applicability. This change, if approved, will result in a renumbering of definitions at APC–S–1.

B. Changes to APC–S–1, Section 3— "Specific Criteria for Source of Particular Matter"

#### 1. Paragraph 4—"Fuel Burning"

As it currently exists in the SIP, APC-S-1, Section 3.4(b)—"Combination Boilers"—states that particulate matter emissions from combination boilers involved in fuel burning operations that utilize a mixture of combustibles are allowed emission rates up to 0.30 grains per standard dry cubic foot. Mississippi's July 25, 2010, SIP submission added language to clarify that section 3.4(b) is only applicable to fuel burning operations that utilize a mixture of combustibles "to produce steam or heat water or any other heat transfer medium through indirect means."

### 2. Paragraph 6—''Manufacturing Processes''

Mississippi is amending subparagraph (a) relating to particulate matter emission limits based on process weight rate to clarify that the emission limit listed in that subparagraph applies to the manufacturing process including

source or activity which condense to form particulate matter at ambient temperatures. Direct PM<sub>2.5</sub> emissions include elemental carbon, directly emitted organic carbon, directly emitted sulfate, directly emitted nitrate, and other inorganic particles (including but not limited to crustal material, metals, and sea salt)." 40 CFR 51.1000.

<sup>3</sup> The federal provisions for implementation of the PM<sub>2.5</sub> NAAQS require, after January 1, 2011, that states must consider the condensable fraction of direct PM<sub>2.5</sub> emissions when establishing limits under 40 CFR 51.1009 (Reasonable further progress requirements (RFP)) and 40 CFR 51.1010 (Requirements for reasonably available control technology (RACT) and reasonably available control measures (RACM)). See 40 CFR 51.1002(c) However, Mississippi's adopted definition of "PM2.5 emissions" does not explicitly include the condensable fraction of direct PM2.5 emissions. EPA notes that if PM<sub>2.5</sub> nonattainment areas are designated within the State in the future, the State's definition of "PM2.5 emissions" may need to be revised to include condensable emissions to ensure that the RFP and RACT/RACM provisions are properly implemented. EPA also notes that Mississippi's PSD permitting program at APC-S-5 already requires sources to account for PM<sub>2.5</sub> condensable emissions when determining PM2.5 emission limitations and PSD applicability.

any associated stacks, vents, outlets, or combination thereof.

#### 3. Paragraph 7—"Open Burning"

Mississippi is amending subparagraph (a)(1) to clarify that fires set for burning of agricultural wastes in the field and/or silvicultural wastes for forest management purposes must obtain a permit from the Mississippi Forestry Commission regardless of whether there is an available Forestry Commission tower servicing the area in which the burning occurs.

#### 4. Paragraph 8—"Incineration"

Mississippi is adding subparagraph (c) to clarify that the particulate matter emission limit for incinerators, 0.2 grains per standard dry cubic foot of flue gas, does not apply to "afterburners, flares, thermal oxidizers, and other similar devices used to reduce the emissions of air pollutants from processes." EPA notes that all particulate matter emissions discharged from such control devices are part of the total emissions from the process unit and are not excluded from determinations of compliance with applicable emission limitations. Mississippi also amended the text of subparagraph (a) to reference subparagraph (c) to further clarify that devices listed at paragraph (c) are not required to apply the particulate matter emission limit for incinerators identified in subparagraph (a).

#### III. Incorporation by Reference

In this rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference certain changes to Mississippi's air pollution control regulation APC-S-1, entitled "Air Emission Regulations for the Prevention, Abatement, and Control of Air Contaminants." Specifically, these changes include the amendments to Section 2—"Definitions" and Section –"Specific Criteria for Sources of Particulate Matter" described in section II, above. EPA has made, and will continue to make, these documents generally available electronically through www.regulations.gov and/or in hard copy at the appropriate EPA office (see the ADDRESSES section of this preamble for more information).

#### **IV. Proposed Action**

EPA is proposing to approve portions of Mississippi's July 25, 2010, SIP submission revising Rule APC–S–1 to add and amend definitions in accordance with federal regulations and

to implement clarifying language. EPA has preliminarily determined that these changes to the Mississippi SIP are in accordance with the Clean Air Act (CAA or Act) and EPA policy and regulations. With the exception of changes in Section 8 related to hazardous air pollutants and the changes in Section 14 related to Mississippi's CAIR provisions, EPA is proposing to approve Mississippi's SIP revisions provided to EPA on July 25, 2010. EPA will consider action on Mississippi's changes to its CAIR provisions and its hazardous air pollutants provisions in a separate action.

### V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. See 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999):
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because

application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 et seq.

Dated: July 9, 2015.

#### Heather McTeer Toney,

Regional Administrator, Region 4. [FR Doc. 2015–17744 Filed 7–17–15; 8:45 am]

BILLING CODE 6560-50-P

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R04-OAR-2015-0368; FRL-9930-77-Region 4]

Approval and Promulgation of Implementation Plans; North Carolina; Nitrogen Dioxide and Sulfur Dioxide National Ambient Air Quality Standards Revisions

**AGENCY:** Environmental Protection

Agency (EPA).

**ACTION:** Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan revision submitted by the State of North Carolina, through the North Carolina Department of Environment and Natural Resources on August 13, 2012, pertaining to definition changes for the Nitrogen Dioxide and Sulfur Dioxide National Ambient Air Quality Standards. EPA is approving this SIP revision because the State has demonstrated that it is consistent with the Clean Air Act. In the Final Rules

section of this issue of the **Federal Register**, EPA is approving the State's implementation plan revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule.

**DATES:** Written comments must be received on or before August 19, 2015.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R04-OAR-2015-0368, by one of the following methods:

- 1. www.regulations.gov: Follow the on-line instructions for submitting comments.
  - 2. Email: R4-ARMS@epa.gov.
  - 3. Fax: (404) 562-9019.
- 4. Mail: "EPA-R04-OAR-2015-0368," Air Regulatory Management Section (formerly the Regulatory Development Section), Air Planning and Implementation Branch (formerly the Air Planning Branch), Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960.
- 5. Hand Delivery or Courier: Lynorae Benjamin, Chief, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Zuri Farngalo, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9152. Mr. Farngalo can also be reached via electronic mail at farngalo.zuri@epa.gov.

**SUPPLEMENTARY INFORMATION:** For additional information see the direct final rule which is published in the Rules Section of this **Federal Register**. A detailed rationale for the approval is set forth in the direct final rule. If no

adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

Dated: July 6, 2015.

#### Heather McTeer Toney,

 $\label{eq:Regional Administrator, Region 4.} \\ [\text{FR Doc. 2015-17682 Filed 7-17-15; 8:45 am}]$ 

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R04-OAR-2012-0696; FRL-9930-85-Region 4]

Approval and Promulgation of Implementation Plans; Georgia Infrastructure Requirements for the 2008 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection

Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve portions of the May 14, 2012, State Implementation Plan (SIP) submission, provided by the Georgia Department of Natural Resources, Environmental Protection Division (hereafter referred to as GA EPD) for inclusion into the Georgia SIP. This proposal pertains to the Clean Air Act (CAA or the Act) infrastructure requirements for the 2008 8-hour ozone national ambient air quality standards (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an "infrastructure" SIP. GA EPD certified that the Georgia SIP contains provisions that ensure the 2008 8-hour ozone NAAQS is implemented, enforced, and maintained in Georgia. With the exception of provisions pertaining to prevention of significant deterioration (PSD) permitting and interstate transport requirements, EPA is proposing to approve Georgia's infrastructure SIP submission provided to EPA on May 14, 2012, as satisfying the required infrastructure elements for the 2008 8-hour ozone NAAQS.

**DATES:** Written comments must be received on or before August 19, 2015.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R04-OAR-2012-0696, by one of the following methods:

- 1. www.regulations.gov: Follow the on-line instructions for submitting comments.
  - 2. Email: R4-ARMS@epa.gov.
  - 3. Fax: (404) 562-9019.
- 4. Mail: "EPA-R04-OAR-2012-0696," Air Regulatory Management Section, (formerly the Regulatory Development Section), Air Planning and Implementation Branch, (formerly the Air Planning Branch) Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303-8960.
- 5. Hand Delivery or Courier: Lynorae Benjamin, Chief, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

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#### FOR FURTHER INFORMATION CONTACT:

Nacosta C. Ward, *Air Regulatory Management Section*, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9140. Ms. Ward can be reached via electronic mail at *ward.nacosta@epa.gov*.

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#### I. Background

On March 27, 2008, EPA promulgated a revised NAAQS for ozone based on 8hour average concentrations. EPA revised the level of the 8-hour ozone

NAAQS to 0.075 parts per million. See 77 FR 16436. Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. States were required to submit such SIPs for the 2008 8-hour ozone NAAOS to EPA no later than March 2011.1

Today's action is proposing to approve Georgia's infrastructure submission for the applicable requirements of the 2008 8-hour ozone NAAQS, with the exception of the PSD permitting requirements for major sources of sections 110(a)(2)(C), (D)(i)(II) prong 3 and (J) and the interstate transport requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4). With respect to Georgia's infrastructure SIP submission related to provisions pertaining to interstate transport requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs, 1, 2, and 4), EPA is not proposing any action today regarding these requirements and will act on these requirements in a separate action. On March 18, 2015, EPA approved Georgia's May 14, 2012, infrastructure SIP submission regarding the PSD permitting requirements for major sources of sections 110(a)(2)(C), (D)(i)(II) prong 3 and (J) for the 2008 8hour NAAQS. See 80 FR 14019. Therefore, EPA is not proposing any action in today's proposed rulemaking pertaining to the PSD components of sections 110(a)(2)(C), D)(i)(II) prong 3, and (J). For the aspects of Georgia's submittal proposed for approval today, EPA notes that the Agency is not approving any specific rule, but rather proposing that Georgia's already approved SIP meets certain CAA requirements.

<sup>&</sup>lt;sup>1</sup> In these infrastructure SIP submissions states generally certify evidence of compliance with sections 110(a)(1) and (2) of the CAA through a combination of state regulations and statutes, some of which have been incorporated into the federallyapproved SIP. In addition, certain federally approved, non-SIP regulations may also be appropriate for demonstrating compliance with sections 110(a)(1) and (2). Unless otherwise indicated, the Georgia Rules for Air Quality (also referred to as "Rules" or "Regulations") of the Georgia SIP cited throughout this rulemaking have been approved into Georgia's federally-approved SIP. The state statutes cited from the Georgia Air Quality Act Article 1: Air Quality (also referred to as "O.C.G.A.") throughout this rulemaking however, are not approved into the Georgia SIP.

### II. What elements are required under Sections 110(a)(1) and (2)?

Section 110(a) of the CAA requires states to submit SIPs to provide for the implementation, maintenance, and enforcement of a new or revised NAAQS within three years following the promulgation of such NAAQS, or within such shorter period as EPA may prescribe. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances. In particular, the data and analytical tools available at the time the state develops and submits the SIP for a new or revised NAAOS affects the content of the submission. The contents of such SIP submissions may also vary depending upon what provisions the state's existing SIP already contains. In the case of the 2008 8-hour ozone NAAQS, states typically have met the basic program elements required in section 110(a)(2) through earlier SIP submissions in connection with the 1997 8-hour ozone NAAQS.

More specifically, section 110(a)(1) provides the procedural and timing requirements for SIPs. Section 110(a)(2) lists specific elements that states must meet for "infrastructure" SIP requirements related to a newly established or revised NAAQS. As mentioned above, these requirements include basic SIP elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. The requirements of section 110(a)(2) are summarized below and in EPA's September 13, 2013, memorandum entitled "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)."2

- 110(a)(2)(A): Emission Limits and Other Control Measures
- 110(a)(2)(B): Ambient Air Quality Monitoring/Data System

- 110(a)(2)(C): Programs for Enforcement of Control Measures and for Construction or Modification of Stationary Sources <sup>3</sup>
- 110(a)(2)(D)(i)(I) and (II): Interstate Pollution Transport
- 110(a)(2)(D)(ii): Interstate Pollution Abatement and International Air Pollution
- 110(a)(2)(E): Adequate Resources and Authority, Conflict of Interest, and Oversight of Local Governments and Regional Agencies
- 110(a)(2)(F): Stationary Source Monitoring and Reporting
  - 110(a)(2)(G): Emergency Powers
  - 110(a)(2)(H): SIP revisions
- 110(a)(2)(I): Plan Revisions for Nonattainment Areas <sup>4</sup>
- 110(a)(2)(J): Consultation with Government Officials, Public Notification, and PSD and Visibility Protection
- 110(a)(2)(K): Air Quality Modeling and Submission of Modeling Data
  - 110(a)(2)(L): Permitting fees
- 110(a)(2)(M): Consultation and Participation by Affected Local Entities

# III. What is EPA's approach to the review of infrastructure SIP submissions?

EPA is acting upon the SIP submission from Georgia that addresses the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2008 8-hour ozone NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions "within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof)," and these SIP submissions are to provide for the "implementation, maintenance, and enforcement" of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that "[e]ach such plan" submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as "infrastructure SIP" submissions. Although the term "infrastructure SIP"

does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as "nonattainment SIP" or "attainment plan SIP" submissions to address the nonattainment planning requirements of part D of title I of the CAA, "regional haze SIP" submissions required by EPA rule to address the visibility protection requirements of CAA section 169A, and nonattainment new source review permit program submissions to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions, and section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.<sup>5</sup> EPA therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submissions provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

The following examples of ambiguities illustrate the need for EPA to interpret some section 110(a)(1) and section 110(a)(2) requirements with respect to infrastructure SIP submissions for a given new or revised NAAQS. One example of ambiguity is that section 110(a)(2) requires that "each" SIP submission must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and would create a conflict with the nonattainment provisions in part D of title I of the Act, which specifically address nonattainment SIP

<sup>&</sup>lt;sup>2</sup> Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) because SIPs incorporating necessary local nonattainment area controls are not due within three years after promulgation of a new or revised NAAQS, but rather due at the time the nonattainment area plan requirements are due pursuant to section 172. These requirements are: (1) Submissions required by section 110(a)(2)(C) to the extent that subsection refers to a permit program as required in part D Title I of the CAA; and (2) submissions required by section 110(a)(2)(I) which pertain to the nonattainment planning requirements of part D, Title I of the CAA. Today's proposed rulemaking does not address infrastructure elements related to section 110(a)(2)(I) or the nonattainment planning requirements of 110(a)(2)(C).

<sup>&</sup>lt;sup>3</sup> This rulemaking only addresses requirements for this element as they relate to attainment areas.

<sup>&</sup>lt;sup>4</sup> As mentioned above, this element is not relevant to today's proposed rulemaking.

<sup>&</sup>lt;sup>5</sup> For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

requirements.<sup>6</sup> Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submissions to address nonattainment area requirements are due. For example, section 172(b) requires EPA to establish a schedule for submission of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and section 107(d)(1)(B) allows up to two years, or in some cases three years, for such designations to be promulgated. This ambiguity illustrates that rather than apply all the stated requirements of section 110(a)(2) in a strict literal sense, EPA must determine which provisions of section 110(a)(2) are applicable for a particular infrastructure SIP submission.

Another example of ambiguity within sections 110(a)(1) and 110(a)(2) with respect to infrastructure SIPs pertains to whether states must meet all of the infrastructure SIP requirements in a single SIP submission, and whether EPA must act upon such SIP submission in a single action. Although section 110(a)(1) directs states to submit "a plan" to meet these requirements, EPA interprets the CAA to allow states to make multiple SIP submissions separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submissions to meet the infrastructure SIP requirements, EPA can elect to act on such submissions either individually or in a larger combined action.8 Similarly, EPA interprets the CAA to

allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submission for a given NAAQS without concurrent action on the entire submission. For example, EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submission.<sup>9</sup>

Ambiguities within sections 110(a)(1) and 110(a)(2) may also arise with respect to infrastructure SIP submission requirements for different NAAQS. Thus, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAOS. The states' attendant infrastructure SIP submissions for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure SIP submission for purposes of section 110(a)(2)(B) could be very different for different pollutants because the content and scope of a state's infrastructure SIP submission to meet this element might be very different for an entirely new NAAQS than for a minor revision to an existing NAAQS.<sup>10</sup>

EPA notes that interpretation of section 110(a)(2) is also necessary when EPA reviews other types of SIP submissions required under the CAA. Therefore, as with infrastructure SIP submissions, EPA also has to identify and interpret the relevant elements of section 110(a)(2) that logically apply to these other types of SIP submissions. For example, section 172(c)(7) requires that attainment plan SIP submissions required by part D have to meet the "applicable requirements" of section 110(a)(2). Thus, for example, attainment plan SIP submissions must meet the requirements of section 110(a)(2)(A) regarding enforceable emission limits and control measures and section 110(a)(2)(E)(i) regarding air agency resources and authority. By contrast, it is clear that attainment plan SIP submissions required by part D would not need to meet the portion of section 110(a)(2)(C) that pertains to the PSD

program required in part C of title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submission may implicate some elements of section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of section 110(a)(1) and section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of section 110(a)(1) and section 110(a)(2)in the context of acting on a particular SIP submission. In other words, EPA assumes that Congress could not have intended that each and every SIP submission, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submissions against the list of elements in section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submissions for particular elements.<sup>11</sup> EPA most recently issued guidance for infrastructure SIPs on September 13, 2013 (2013 Guidance). 12 EPA developed this document to provide states with upto-date guidance for infrastructure SIPs for any new or revised NAAOS. Within this guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure

<sup>&</sup>lt;sup>6</sup> See, e.g., "Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NOx SIP Call; Final Rule," 70 FR 25162, at 25163—65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

<sup>&</sup>lt;sup>7</sup> EPA notes that this ambiguity within section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submission of certain types of SIP submissions in designated nonattainment areas for various pollutants. Note, e.g., that section 182(a)(1) provides specific dates for submission of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

<sup>8</sup> See, e.g., "Approval and Promulgation of Implementation Plans: New Mexico: Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting," 78 FR 4339 (January 22, 2013) (EPA's final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA's 2008 PM2.5 NSR rule), and "Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Infrastructure and Interstate Transport Requirements for the 2006 PM<sub>2.5</sub> NAAQS," (78 FR 4337) (January 22, 2013) (EPA's final action on the infrastructure SIP for the 2006 PM<sub>2.5</sub> NAAQS).

<sup>&</sup>lt;sup>9</sup> On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other section 110(a)(2) infrastructure SIP elements of Tennessee's December 14, 2007 submittal.

 $<sup>^{10}\,\</sup>mathrm{For}$  example, implementation of the 1997 PM<sub>2.5</sub> NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

<sup>&</sup>lt;sup>11</sup>EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

<sup>&</sup>lt;sup>12</sup> "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)," Memorandum from Stephen D. Page, September 13, 2013.

SIP submissions.<sup>13</sup> The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). Significantly, EPA interprets sections 110(a)(1) and 110(a)(2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.

As an example, section 110(a)(2)(E)(ii) is a required element of section 110(a)(2) for infrastructure SIP submissions. Under this element, a state must meet the substantive requirements of section 128, which pertain to state boards that approve permits or enforcement orders and heads of executive agencies with similar powers. Thus, EPA reviews infrastructure SIP submissions to ensure that the state's implementation plan appropriately addresses the requirements of section 110(a)(2)(E)(ii) and section 128. The 2013 Guidance explains EPA's interpretation that there may be a variety of ways by which states can appropriately address these substantive statutory requirements, depending on the structure of an individual state's permitting or enforcement program (e.g., whether permits and enforcement orders are approved by a multi-member board or by a head of an executive agency). However they are addressed by the state, the substantive requirements of section 128 are necessarily included in EPA's evaluation of infrastructure SIP submissions because section 110(a)(2)(E)(ii) explicitly requires that the state satisfy the provisions of section

As another example, EPA's review of infrastructure SIP submissions with respect to the PSD program requirements in sections 110(a)(2)(C), (D)(i)(II), and (J) focuses upon the structural PSD program requirements contained in part C and EPA's PSD regulations. Structural PSD program requirements include provisions necessary for the PSD program to address all regulated sources and NSR

pollutants, including greenhouse gases. By contrast, structural PSD program requirements do not include provisions that are not required under EPA's regulations at 40 CFR 51.166 but are merely available as an option for the state, such as the option to provide grandfathering of complete permit applications with respect to the 2012 PM<sub>2.5</sub> NAAQS. Accordingly, the latter optional provisions are types of provisions EPA considers irrelevant in the context of an infrastructure SIP action.

For other section 110(a)(2) elements, however, EPA's review of a state's infrastructure SIP submission focuses on assuring that the state's SIP meets basic structural requirements. For example, section 110(a)(2)(C) includes, among other things, the requirement that states have a program to regulate minor new sources. Thus, EPA evaluates whether the state has an EPAapproved minor new source review program and whether the program addresses the pollutants relevant to that NAAQS. In the context of acting on an infrastructure SIP submission, however, EPA does not think it is necessary to conduct a review of each and every provision of a state's existing minor source program (i.e., already in the existing SIP) for compliance with the requirements of the CAA and EPA's regulations that pertain to such

programs.

With respect to certain other issues, EPA does not believe that an action on a state's infrastructure SIP submission is necessarily the appropriate type of action in which to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction that may be contrary to the CAA and EPA's policies addressing such excess emissions ("SSM"); (ii) existing provisions related to "director's variance" or "director's discretion" that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by EPA; and (iii) existing provisions for PSD programs that may be inconsistent with current requirements of EPA's "Final NSR Improvement Rule," 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) ("NSR Reform"). Thus, EPA believes it may approve an infrastructure SIP submission without scrutinizing the totality of the existing SIP for such potentially deficient provisions and may approve the submission even if it is

aware of such existing provisions. $^{14}$  It is important to note that EPA's approval of a state's infrastructure SIP submission should not be construed as explicit or implicit re-approval of any existing potentially deficient provisions that relate to the three specific issues just described.

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of "implementation, maintenance, and enforcement" of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

For example, EPA's 2013 Guidance gives simpler recommendations with respect to carbon monoxide than other NAAQS pollutants to meet the visibility requirements of section 110(a)(2)(D)(i)(II), because carbon monoxide does not affect visibility. As a result, an infrastructure SIP submission for any future new or revised NAAOS for carbon monoxide need only state this fact in order to address the visibility prong of section 110(a)(2)(D)(i)(II).

Finally, EPA believes that its approach with respect to infrastructure SIP requirements is based on a reasonable reading of sections 110(a)(1)

 $<sup>^{13}\,\</sup>mathrm{EPA's}$  September 13, 2013, guidance did not make recommendations with respect to infrastructure SIP submissions to address section 110(a)(2)(D)(i)(I). EPA issued the guidance shortly after the U.S. Supreme Court agreed to review the D.C. Circuit decision in *EME Homer City*, 696 F.3d7 (D.C. Cir. 2012) which had interpreted the requirements of section 110(a)(2)(D)(i)(I). In light of the uncertainty created by ongoing litigation, EPA elected not to provide additional guidance on the requirements of section 110(a)(2)(D)(i)(I) at that time. As the guidance is neither binding nor required by statute, whether EPA elects to provide guidance on a particular section has no impact on a state's CAA obligations.

 $<sup>^{14}\,\</sup>mathrm{By}$  contrast, EPA notes that if a state were to include a new provision in an infrastructure SIP submission that contained a legal deficiency, such as a new exemption for excess emissions during SSM events, then EPA would need to evaluate that provision for compliance against the rubric of applicable CAA requirements in the context of the action on the infrastructure SIP.

and 110(a)(2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a "SIP call" whenever the Agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.<sup>15</sup> Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions. 16 Significantly, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action.17

#### IV. What is EPA's analysis of how Georgia addressed the elements of Sections 110(a)(1) and (2) "Infrastructure" Provisions?

The Georgia infrastructure submission addresses the provisions of sections 110(a)(1) and (2) as described below.

1. 110(a)(2)(A) Emission limits and other control measures: There are several provisions within the Georgia Rules for Air Quality that provide GA EPD with the necessary authority to adopt and enforce air quality controls, which include enforceable emission limitations and other control measures. Rule 391-3-1-.01 "Definitions" provides definitions of emissions limitations, controls, and standards for Georgia. Rules 391-3-1-.02 "Provisions" and 391-3-1-.03 "Permits" provides emissions limitations, control measures and compliance schedules and provides Georgia with the authority to enforce such provisions for ozone. EPA has made the preliminary determination that the provisions contained in these rules are adequate to protect the 2008 8hour ozone NAAQS in the State.

In this action, EPA is not proposing to approve or disapprove any existing State provisions with regard to excess emissions during startup, shutdown or malfunction (SSM) of operations at a facility. EPA believes that a number of states have SSM provisions which are contrary to the CAA and existing EPA guidance, "State Implementation Plans: Policy Regarding Excess Emissions During Malfunctions, Startup, and Shutdown" (September 20, 1999), and the Agency is addressing such state regulations in a separate action.<sup>18</sup> In the meantime, EPA encourages any state having a deficient SSM provision to take steps to correct it as soon as possible.

Additionally, in this action, EPA is not proposing to approve or disapprove any existing State rules with regard to director's discretion or variance provisions. EPA believes that a number of states have such provisions which are contrary to the CAA and existing EPA guidance (52 FR 45109 (November 24, 1987)), and the Agency plans to take action in the future to address such state regulations. In the meantime, EPA encourages any state having a director's

discretion or variance provision which is contrary to the CAA and EPA guidance to take steps to correct the deficiency as soon as possible.

2. 110(a)(2)(B) Ambient air quality monitoring/data system: SIPs are required to provide for the establishment and operation of ambient air quality monitors; the compilation and analysis of ambient air quality data; and the submission of these data to EPA upon request. Georgia Air Quality Act Article 1: Air Quality (O.C.G.A. Section 12-9-6 (b)(13) Powers and duties of director as to air quality generally) along with the Georgia Annual Monitoring Network Plan, provides GA EPD with the authority to monitor ambient air quality in Georgia through an ambient air quality monitoring system in the State, which includes the monitoring of ozone at appropriate locations throughout the state using the EPA approved Federal Reference Method or equivalent monitors. Annually, States develop and submit to EPA for approval statewide ambient monitoring network plans consistent with the requirements of 40 CFR parts 50, 53, and 58. The annual network plan involves an evaluation of any proposed changes to the monitoring network, includes the annual ambient monitoring network design plan and a certified evaluation of the agency's ambient monitors and auxiliary support equipment.19 The latest monitoring network plan for Georgia was submitted to EPA on June 1, 2014, and on November 7, 2014, EPA approved this plan. Georgia's approved monitoring network plan can be accessed at www.regulations.gov using Docket ID No. EPA-R04-OAR-2012-0696. EPA has made the preliminary determination that Georgia's SIP and practices are adequate for the ambient air quality monitoring and data system related to the 2008 8-hour ozone

3. 110(a)(2)(C) Program for enforcement of control measures including review of proposed new sources: This element consists of three sub-elements; enforcement, state-wide regulation of new and modified minor sources and minor modifications of major sources; and preconstruction permitting of major sources and major modifications in areas designated attainment or unclassifiable for the subject NAAQS as required by CAA title I part C (i.e., the major source

PSD program). To meet these obligations, Georgia cited Rules 391–3–

<sup>&</sup>lt;sup>15</sup> For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See "Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions," 74 FR 21639 (April 18, 2011).

<sup>&</sup>lt;sup>16</sup> EPA has used this authority to correct errors in past actions on SIP submissions related to PSD programs. See "Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule," 75 FR 82536 (December 30, 2010). EPA has previously used its authority under CAA section 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, e.g., 61 FR 38664 (July 25, 1996) and 62 FR 34641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062 (November 16, 2004) (corrections to California SIP); and 74 FR 57051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

<sup>&</sup>lt;sup>17</sup> See, e.g., EPA's disapproval of a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, e.g., 75 FR 42342 at 42344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4540 (Jan. 26, 2011) (final disapproval of such provisions).

<sup>18</sup> On May 22, 2015, the EPA Administrator signed a final action entitled, "State Implementation Plans: Response to Petition for Rulemaking; Restatement and Update of EPA's SSM Policy Applicable to SIPs; Findings of Substantial Inadequacy; and SIP Calls to Amend Provisions Applying to Excess Emissions During Periods of Startup, Shutdown, and Malfunction." The prepublication version of this rule is available at http://www.epa.gov/airquality/urbanair/sipstatus/emissions.html.

<sup>&</sup>lt;sup>19</sup>On occasion, proposed changes to the monitoring network are evaluated outside of the network plan approval process in accordance with 40 CFR part 58.

1-.07 "Inspections and Investigations," Rule 391–3–1–.09 "Enforcement," and Rule 391-3-1-.03(1), "Construction (SIP) Permit" along with the Georgia Air Quality Act Article 1: Air Quality (O.C.G.A. Sections 12-9-13 Proceedings for enforcement and 12-9-7 Permit required; application; issuance; revocation, suspension, or amendment) each of which pertain to enforcement and permitting of any new major stationary source or any project at an existing major stationary source in an area designated as attainment or unclassifiable as well as regulation of minor stationary sources. In this action, EPA is only proposing to approve Georgia's infrastructure SIP submission for the 2008 8-hour ozone NAAQS with respect to the general requirement in section 110(a)(2)(C) to include a program in the SIP that provides for the enforcement of emission limits and control measures on sources of oxides of nitrogen (NOx) and volatile organic compounds (VOCs) and the regulation of minor sources and modifications to assist in the protection of air quality in nonattainment, attainment or unclassifiable areas.

Enforcement: GA EPD's above-described, SIP-approved regulations provide for enforcement of ozone precursor (VOC and NOx) emission limits and control measures.

Preconstruction PSD Permitting for Major Sources: With respect to Georgia's May 14, 2012, infrastructure SIP submission related to the preconstruction PSD permitting requirements for major sources of section 110(a)(2)(C), EPA took final action to approve these provisions for the 2008 8-hour ozone NAAQS on March 18, 2015. See 80 FR 14019.

Regulation of minor sources and modifications: Section 110(a)(2)(C) also requires the SIP to include provisions that govern the minor source program that regulates emissions of the 2008 8-hour ozone NAAQS. Rule 391–3–1–.03(1), "Construction (SIP) Permit" governs the preconstruction permitting of modifications and construction of minor stationary sources.

EPA has made the preliminary determination that Georgia's SIP and practices are adequate for enforcement of control measures and regulation of minor sources and modifications related to the 2008 8-hour ozone NAAQS.

4. 110(a)(2)(D)(i)(I) and (II) Interstate Pollution Transport: Section 110(a)(2)(D)(i) has two components; 110(a)(2)(D)(i)(I) and 110(a)(2)(D)(II). Each of these components have two subparts resulting in four distinct components, commonly referred to as "prongs," that must be addressed in

infrastructure SIP submissions. The first two prongs, which are codified in section 110(a)(2)(D)(i)(I), are provisions that prohibit any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state ("prong 1"), and interfering with maintenance of the NAAQS in another state ("prong 2"). The third and fourth prongs, which are codified in section 110(a)(2)(D)(i)(II), are provisions that prohibit emissions activity in one state interfering with measures required to prevent significant deterioration of air quality in another state ("prong 3"), or to protect visibility in another state ("prong 4"). With respect to Georgia's infrastructure SIP submissions related to the interstate transport requirements of section 110(a)(2)(D)(i)(I) and 110(a)(2)(D)(i)(II) (prongs 1 through 4), EPA is not proposing any action today regarding these requirements. With respect to Georgia's May 14, 2012, infrastructure SIP submission related to the preconstruction PSD permitting requirements for major sources of section 110(a)(2)(D)(i)(II) (prong 3), EPA took final action to approve these provisions for the 2008 8-hour ozone NAAQS on March 18, 2015. See 80 FR 14019. EPA will act on prongs 1, 2, and 4 of section 110(a)(2)(D)(i)(I) and (II) in a separate action.

5. 110(a)(2)(D)(ii) Interstate Pollution Abatement and International Air Pollution: Section 110(a)(2)(D)(ii) requires SIPs to include provisions ensuring compliance with sections 115 and 126 of the Act, relating to interstate and international pollution abatement. Rule 391-3-1-.02 "Provisions" provides how GA EPD will notify neighboring states of potential impacts from new or modified sources consistent with the requirements of 40 CFR 51.166. In addition, Georgia does not have any pending obligation under sections 115 and 126 of the CAA. Accordingly, EPA has made the preliminary determination that Georgia's SIP and practices are adequate for ensuring compliance with the applicable requirements relating to interstate and international pollution abatement for the 2008 8-hour ozone

6. 110(a)(2)(E) Adequate Resources and Authority, Conflict of Interest, and Oversight of Local Governments and Regional Agencies: Section 110(a)(2)(E) requires that each implementation plan provide (i) necessary assurances that the State will have adequate personnel, funding, and authority under state law to carry out its implementation plan, (ii) that the State comply with the requirements respecting State Boards

pursuant to section 128 of the Act, and (iii) necessary assurances that, where the State has relied on a local or regional government, agency, or instrumentality for the implementation of any plan provision, the State has responsibility for ensuring adequate implementation of such plan provisions. EPA is proposing to approve Georgia's SIP as meeting the requirements of section 110(a)(2)(E). EPA's rationale for today's proposal respecting subelements (i), (ii), and (iii) is described below.

In support of EPA's proposal to approve sub-elements 110(a)(2)(E)(i) and (iii), EPA notes that GA EPD is responsible for promulgating rules and regulations for the NAAQS, emissions standards general policies, a system of permits, and fee schedules for the review of plans, and other planning needs. Georgia's infrastructure SIP submission cites Georgia Air Quality Act Article 1: Air Quality (O.C.G.A. Section 12–9–10 Permit related fees; costs of public notice and Rule 391–3– 1-.03(9) "Georgia Air Permit Fee System" which provides the State's adequate funding and authority and rules for permit fees. Additionally, as evidence of the adequacy of GA EPD's resources, EPA submitted a letter to Georgia on March 26, 2014, outlining 105 grant commitments and the current status of these commitments for fiscal vear 2013. The letter EPA submitted to Georgia can be accessed at www.regulations.gov using Docket ID No. EPA-R04-OAR-2012-0696. Annually, states update these grant commitments based on current SIP requirements, air quality planning, and applicable requirements related to the NAAQS. Georgia satisfactorily met all commitments agreed to in the Air Planning Agreement for fiscal year 2013, therefore Georgia's grants were finalized and closed out.

With respect to the requirements of section 110(a)(2)(E)(ii) pertaining the state board requirements of CAA section 128, Georgia's infrastructure SIP submission cites Georgia Air Quality Act Article 1: Air Quality (O.C.G.A. Section 12-9-5 Powers and duties of Board of Natural Resources as to air quality generally) which provides the powers and duties of the Board of Natural Resources as to air quality and provides that at least a majority of members of this board represent the public interest and not derive any significant portion of income from persons subject to permits or enforcement orders and that potential conflicts of interest will be adequately disclosed. This provision has been incorporated into the federally approved SIP. Collectively, these rules and commitments provide evidence that GA EPD has adequate personnel, funding, and legal authority under state law to carry out the state's implementation plan and related issues to ensure that conflicts of interest are adequately addressed. EPA has made the preliminary determination that Georgia has adequate resources and authority to satisfy sections 110(a)(2)(E)(i), (ii), and (iii) of the 2008 8-hour ozone NAAQS.

7. 110(a)(2)(F) Stationary Source Monitoring and Reporting: Georgia's infrastructure SIP submission describes how the State establishes requirements for emissions compliance testing and utilizes emissions sampling and analysis. It further describes how the State ensures the quality of its data through observing emissions and monitoring operations. GA EPD uses these data to track progress towards maintaining the NAAQS, develop control and maintenance strategies, identify sources and general emission levels, and determine compliance with emission regulations and additional EPA requirements. Georgia meets these requirements through the Georgia Air Quality Act Article 1: Air Quality (O.C.G.A. Section 12–9–5(b)(6) *Powers* and duties of Board of Natural Resources as to air quality generally), Rules 391-3-1-.02(3) "Sampling," 391-3-1-.02(6)(b) "General Monitoring and Reporting Requirements," 391-3-1-.02(6) "Source Monitoring," 391-3-1-.02(7) "Prevention of Significant Deterioration of Air Quality," 391-3-1-.02(11) "Compliance Assurance Monitoring," and, 391–3–1–.03 "Permits."

In addition, Rule 391–3–1-.02(3) "Sampling" <sup>20</sup> allows for the use of credible evidence in the event that the GA EPD Director has evidence that a source is violating an emission standard or permit condition, the Director may require that the owner or operator of any source submit to the Director any information necessary to determine the compliance status of the source. In addition, EPA is unaware of any provision preventing the use of credible evidence in the Georgia SIP.

Georgia is required to submit emissions data to EPA for purposes of the National Emissions Inventory (NEI). The NEI is EPA's central repository for air emissions data. EPA published the Air Emissions Reporting Rule (AERR) on December 5, 2008, which modified the requirements for collecting and reporting air emissions data. See 73 FR 76539. The AERR shortened the time

states had to report emissions data from 17 to 12 months, giving states one calendar year to submit emissions data. All states are required to submit a comprehensive emissions inventory every three years and report emissions for certain larger sources annually through EPA's online Emissions Inventory System. States report emissions data for the six criteria pollutants and the precursors that form them—NO<sub>X</sub>, sulfur dioxide, ammonia, lead, carbon monoxide, particulate matter, and volatile organic compounds. Many states also voluntarily report emissions of hazardous air pollutants. Georgia made its latest update to the 2011 NEI on June 10, 2014. EPA compiles the emissions data, supplementing it where necessary, and releases it to the general public through the Web site http://www.epa.gov/ttn/ chief/eiinformation.html. EPA has made the preliminary determination that Georgia's SIP and practices are adequate for the stationary source monitoring systems obligations for the 2008 8-hour ozone NAAQS.

8. 110(a)(2)(G) Emergency powers: This section requires that states demonstrate authority comparable with section 303 of the CAA and adequate contingency plans to implement such authority. Georgia's infrastructure SIP submission cites air pollution emergency episodes and preplanned abatement strategies in the Georgia Air Quality Act: Article 1: Air Quality (O.C.G.A. Sections 12-9-2 Declaration of public policy, 12-9-6 Powers and duties of director as to air quality generally, 12–9–12 Injunctive relief, 12– 9–13 Proceedings for enforcement, and 12-9-14 Powers of director in situations involving imminent and substantial danger to public health), and Rule 391-3-1 .04 "Air Pollution Episodes." O.C.G.A. Section 12-9-2 provides "[i]t is declared to be the public policy of the state of Georgia to preserve, protect, and improve air quality. . . to attain and maintain ambient air quality standards so as to safeguard the public health, safety, and welfare." O.C.G.A. Section 12-9-6(b)(10) provides the Director of EPD authority to "issue orders as may be necessary to enforce compliance with [the Georgia Air Quality Act Article 1: Air Quality (O.C.G.A)] and all rules and regulations of this article." O.C.G.A. Section 12-9-12 provides that "[w]henever in the judgment of the director any person has engaged in or is about to engage in any act or practice which constitutes or will constitute an unlawful action under [the Georgia Air Quality Act Article 1: Air Quality (O.C.G.A)], he may make application to

the superior court of the county in which the unlawful act or practice has been or is about to be engaged in, or in which jurisdiction is appropriate, for an order enjoining such act or practice or for an order requiring compliance with this article. Upon a showing by the director that such person has engaged in or is about to engage in any such act or practice, a permanent or temporary injunction, restraining order, or other order shall be granted without the necessity of showing lack of an adequate remedy of law." O.C.G.A. Section 12-19-13 specifically pertains to enforcement proceedings when the Director of EPD has reason to believe that a violation of any provision of the Georgia Air Quality Act Article 1: Air Quality (O.C.G.A), or environmental rules, regulations or orders have occurred. O.C.G.A. Section 12-9-14 also provides that the Governor, may issue orders as necessary to protect the health of persons who are, or may be, affected by a pollution source or facility after "consult[ation] with local authorities in order to confirm the correctness of the information on which action proposed to be taken is based and to ascertain the action which such authorities are or will be taking.

Rule 391-3-1-.04 "Air Pollution Episodes'' provides that the Director of EPD "will proclaim that an Air Pollution Alert, Air Pollution Warning, or Air Pollution Emergency exists when the meteorological conditions are such that an air stagnation condition is in existence and/or the accumulation of air contaminants in any place is attaining or has attained levels which could, if such levels are sustained or exceeded, lead to a substantial threat to the health of persons in the specific area affected." Collectively the cited provisions provide that Georgia EPD demonstrate authority comparable with section 303 of the CAA and adequate contingency plans to implement such authority in the state. EPA has made the preliminary determination that Georgia's SIP and practices are adequate to satisfy the emergency powers obligations of the 2008 8-hour ozone NAAQS.

9. 110(a)(2)(H) SIP revisions: GA EPD is responsible for adopting air quality rules and revising SIPs as needed to attain or maintain the NAAQS in Georgia. Georgia Air Quality Act: Article 1: Air Quality (O.C.G.A. Section 12–9–6(b)(12), 12–9–6(b)(13) Powers and duties of director as to air quality generally) provides Georgia the authority to implement the CAA and submit SIP revisions whenever the NAAQS are revised. These provisions also provide GA EPD the ability and authority to respond to calls for SIP

 $<sup>^{\</sup>rm 20}\,\rm This$  rule is not approved into the federally approved SIP.

revisions, and Georgia has provided a number of SIP revisions over the years for implementation of the NAAQS. Accordingly, EPA has made the preliminary determination that Georgia's SIP and practices adequately demonstrate a commitment to provide future SIP revisions related to the 2008 8-hour ozone NAAQS, when necessary.

10. 110(a)(2)(J) Consultation with Government Officials, Public Notification, and PSD and Visibility *Protection:* EPA is proposing to approve Georgia's infrastructure SIP for the 2008 8-hour ozone NAAQS with respect to the general requirement in section 110(a)(2)(J) to include a program in the SIP that complies with the applicable consultation requirements of section 121, the public notification requirements of section 127, and visibility protection. With respect to Georgia's infrastructure SIP submission related to the preconstruction PSD permitting, EPA took final action to approve Georgia's May 14, 2012, 2008 8hour ozone NAAQS infrastructure SIP for these requirements on March 18, 2015. See 80 FR 14019. EPA's rationale for its proposed action regarding applicable consultation requirements of section 121, the public notification requirements of section 127, and the visibility requirements is described below.

Consultation with government officials (121 consultation): Section 110(a)(2)(J) of the CAA requires states to provide a process for consultation with local governments, designated organizations and federal land managers (FLMs) carrying out NAAQS implementation requirements pursuant to section 121 relative to consultation. Georgia Air Quality Act: Article 1: Air Quality (O.C.G.A. Section 12–9–5(b)(17) Powers and duties of Board of Natural Resources as to air quality generally), Georgia Administrative Procedures Act (O.C.G.A. Section 50–13–4 Procedural requirements for adoption, amendment, or repeal of rules; emergency rules; limitation on action to contest rule; legislative override), and Rule 391–3–1– .02(7) "Prevention of Significant Deterioration (PSD)" as it relates to Class I areas along with the Regional Haze SIP Plan provide for consultation with government officials whose jurisdictions might be affected by SIP development activities. These consultation procedures were developed in coordination with the transportation partners in the State and are consistent with the approaches used for development of mobile inventories for SIPs. Implementation of transportation conformity as outlined in the consultation procedures requires GA

EPD to consult with federal, state and local transportation and air quality agency officials on the development of motor vehicle emissions budgets. The Regional Haze SIP provides for consultation between appropriate state, local, and tribal air pollution control agencies as well as the corresponding Federal Land Managers.

Public notification (127 public notification): GA EPD has public notice mechanisms in place to notify the public of ozone and other pollutant forecasting, including an air quality monitoring Web site providing ground level ozone alerts, http:// www.georgiaair.org/smogforecast/. Regulation 391–3–1–.04, "Air Pollution Episodes," requires that EPD notify the public of any air pollution episode or NAAOS violation. Additionally, the Georgia SIP process affords the public an opportunity to participate in regulatory and other efforts to improve air quality by holding public hearings for interested persons to appear and submit written or oral comments.

Visibility Protection: EPA's September 2013 Infrastructure SIP Guidance notes that EPA does not generally treat the visibility protection aspects of section  $110(a)(2)(\overline{J})$  as applicable for purposes of the infrastructure SIP approval process. EPA recognizes that states are subject to visibility protection and regional haze program requirements under Part C of the Act (which includes sections 169A and 169B). However, in the event of the establishment of a new primary NAAQS, the visibility protection and regional haze program requirements under part C do not change. Thus, EPA concludes there are no new applicable visibility protection obligations under section 110(a)(2)(J) as a result of the 2008 8-hour ozone NAAQS that need to be addressed in Georgia's infrastructure SIP submission as it relates to visibility protection.

EPA has made the preliminary determination that Georgia's SIP and practices adequately demonstrate the State's ability to provide consultation with government officials, public notification related to the 2008 8-hour ozone NAAQS when necessary, and, as explained above, is sufficient for visibility protection for this element.

11. 110(a)(2)(K) Air Quality Modeling and Submission of Modeling Data:
Section 110(a)(2)(K) of the CAA requires that SIPs provide for performing air quality modeling so that effects on air quality of emissions from NAAQS pollutants can be predicted and submission of such data to the USEPA can be made. Regulation 391–3–1–.02(7)(b)(8), "Prevention of Significant Deterioration of Air Quality (PSD)-Air

Quality Models," incorporates by reference 40 CFR 52.21(l), which specifies that air modeling be conducted in accordance with 40 CFR part 51, Appendix W "Guideline on Air Quality Models." This regulation demonstrates that Georgia has the authority to perform air quality modeling and to provide relevant data for the purpose of predicting the effect on ambient air quality of the 2008 8-hour ozone NAAQS. Additionally, Georgia supports a regional effort to coordinate the development of emissions inventories and conduct regional modeling for several NAAQS, including the 2008 8hour ozone NAAQS, for the Southeastern states. Taken as a whole, Georgia's air quality regulations demonstrate that GA EPD has the authority to provide relevant data for the purpose of predicting the effect on ambient air quality of the 2008 8-hour ozone NAAQS. EPA has made the preliminary determination that Georgia's SIP and practices adequately demonstrate the State's ability to provide for air quality modeling, along with analysis of the associated data, related to the 2008 8-hour ozone NAAQS when necessary.

12. 110(a)(2)(L) Permitting fees: This element necessitates that the SIP require the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under the CAA, a fee sufficient to cover (i) the reasonable costs of reviewing and acting upon any application for such a permit, and (ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other costs associated with any enforcement action), until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under title V.

To satisfy these requirements, Georgia's infrastructure SIP submission cites Rule 391-3-1-.03(9) "Permit Fees," 21 which includes the federally approved title V fee program. Additionally, Georgia's PSD and NNSR programs are funded by title V fees. Georgia's authority to charge fees or require funding for processing PSD and NNSR permits is provided for in the Georgia Air Quality Act: Article 1: Air Quality (O.C.G.A. Section 12-9-10 Permit related fees; costs of public notice). Georgia's fully approved title V operating permit program covers the cost of implementation and enforcement

 $<sup>^{21}\,\</sup>mathrm{This}$  rule is not approved into the federally approved SIP.

of PSD and NNSR permits after they have been issued. EPA has made the preliminary determination that Georgia's practices adequately provide for permitting fees related to the 2008 8-hour ozone NAAQS, when necessary.

13. 110(a)(2)(M) Consultation and Participation by Affected Local Entities: This element requires states to provide for consultation and participation in SIP development by local political subdivisions affected by the SIP. The Georgia Air Quality Act: Article 1: Air Quality (O.C.G.A. Section 12–9–5 (b)(17) Powers and duties of Board of Natural Resources as to air quality generally) establishes "satisfactory processes of consultation and cooperation with local governments or other designated organizations of elected officials or federal agencies for purposes of planning [and implementation]." Furthermore, GA EPD has demonstrated consultation with, and participation by, affected local entities through its work with local political subdivisions during the developing of its Transportation Conformity SIP, and Regional Haze Implementation Plan. EPA has made the preliminary determination that Georgia's SIP and practices adequately demonstrate consultation with affected local entities related to the 2008 8-hour ozone NAAQS, when necessary.

#### V. Proposed Action

With the exception of the PSD permitting requirements for major sources contained in section 110(a)(2)(C), (D)(i)(II) prong 3, and (J) and the interstate transport requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2 and 4), EPA is proposing to approve GA EPD's infrastructure SIP submission, submitted May 14, 2012, for the 2008 8-hour ozone NAAQS because it meets the above described infrastructure SIP requirements. EPA is proposing to approve these portions of Georgia's

infrastructure SIP submission for the 2008 8-hour ozone NAAQS because these aspects of the submission are consistent with section 110 of the CAA. EPA previously acted upon Georgia's infrastructure submission for the PSD permitting requirements for major sources of sections 110(a)(2)(C), (D)(i)(II) prong 3 and (J) on March 18, 2015, and will address prongs 1, 2, and 4 of section 110(a)(2)(D)(i)(I) and (II) in a separate action.

### VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. See 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive

- Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the Georgia SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 et seq.

Dated: July 6, 2015.

#### Heather McTeer Toney,

 $\label{eq:Regional Administrator, Region 4.} \\ [\text{FR Doc. 2015-17740 Filed 7-17-15; 8:45 am}]$ 

BILLING CODE 6560-50-P

### **Notices**

#### Federal Register

Vol. 80, No. 138

Monday, July 20, 2015

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

### DEPARTMENT OF AGRICULTURE

#### Office of the Secretary

Meeting Notice of the National Agricultural Research, Extension, Education, and Economics Advisory Board

AGENCY: Research, Education, and

Economics, USDA.

**ACTION:** Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App 2, Section 1408 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3123), and the Agricultural Act of 2014, the United States Department of Agriculture (USDA) announces an open virtual meeting of the National Agricultural Research, Extension, Education, and Economics Advisory Board.

**DATES:** The National Agricultural Research, Extension, Education, and Economics Advisory Board will meet via teleconference on August 11, 2015, at 2 p.m. Eastern Daylight Time.

**ADDRESSES:** The meeting will take place virtually at the AT&T Meeting Room below. Please follow the pre-registration instructions to ensure your participation in the meeting. Call-In instructions for Tuesday, August 11, 2015, at 2:00 p.m. Eastern Daylight Time: Web Preregistration: Participants may preregister for this teleconference at http://emsp.intellor.com?p=420632& do=register&t=8. Once the participant registers, a confirmation page will display dial-in numbers and a unique PIN, and the participant will also receive an email confirmation of this information.

#### FOR FURTHER INFORMATION CONTACT:

Michele Esch, Designated Federal Officer and Executive Director, National Agricultural Research, Extension, Education, and Economics Advisory Board, U.S. Department of Agriculture, 1400 Independence Avenue SW., STOP 0321, Washington, DC 20250–0321; telephone: (202) 720–3684; fax: (202) 720–6199; or email: nareee@ars.usda.gov. For additional information on the National Agricultural Research, Extension, Education, and Economics Advisory Board, visit http://nareeeab.ree.usda.gov/.

#### SUPPLEMENTARY INFORMATION: On

Tuesday, August 11, 2015, at 2 p.m. Eastern Daylight Time, a virtual meeting of the National Agricultural Research, Extension, Education, and Economics Advisory Board will be conducted to hear the summary of findings and recommendations from the Animal Handling and Welfare Review Panel's Phase II report on the research animal care and well-being policies, procedures, and standards at the Agricultural Research Service. The National Agricultural Research, Extension, Education, and Economics Advisory Board will provide additional advice and recommendations to USDA on the report and hear stakeholder input received at this meeting, as well as, other written comments. The report, entitled Findings and Recommendations on the Phase II Review of the Animal Care and Well-Being at the Agricultural Research Service to the Research, Education, and Economics Under Secretary, is available at www.ree.usda.gov.

This meeting is open to the public and any interested individuals wishing to attend. Opportunity for verbal public comment will be offered on the day of the meeting. Written comments by attendees or other interested stakeholders will be welcomed for the public record before and up to the day of the meeting (by close of business Tuesday, August 11, 2015). All written statements must be sent to Michele Esch, Designated Federal Officer and Executive Director, National Agricultural Research, Extension, Education, and Economics Advisory Board, U.S. Department of Agriculture, 1400 Independence Avenue SW., STOP 0321, Washington, DC 20250-0321; or email: nareee@ars.usda.gov. All statements will become a part of the official record of the National Agricultural Research, Extension, Education, and Economics Advisory Board and will be kept on file for public review in the Research, Education, and Economics Advisory Board Office.

Done at Washington, DC, this 10 day of July, 2015.

#### Ann Bartuska,

Deputy Under Secretary, Research, Education, and Economics.

[FR Doc. 2015-17708 Filed 7-17-15; 8:45 am]

BILLING CODE 3410-03-P

#### **DEPARTMENT OF AGRICULTURE**

#### Submission for OMB Review; Comment Request

July 14, 2015.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB),

OIRA\_Submission@OMB.EOP.GOV or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received by August 19, 2015. Copies of the submission(s) may be obtained by calling (202) 720–8958 or (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

#### Office of the Chief Financial Officer

*Title:* Suspension and Debarment and Drug-Free Workplace Certifications.

OMB Control Number: 0505-New.

Summary of Collection: Suspension and debarment is a discretionary or statutory administrative action taken by Federal agencies to protect the government by excluding person and entities that are not presently responsible from participating in Federal programs or activities. The information will be collected by USDA Federal financial assistance agencies as certifying information concerning applicant suitability in compliance with Federal Suspension and Debarment and Drug-Free Work Place regulations, as defined by 2 CFR parts 180, 417 and Public Law 100-690, Title V, Subtitle D; 41 U.S.C., 8101 et seq., 2 CFR parts 182 and 421.

Need and Use of the Information: The information will be collected using the following Forms: AD-1047, Certification Regarding Debarment, Suspension, and Other Responsibility Matters Primary Covered Transaction; AD-1048, Certification Regarding Debarment, Suspension, Ineligibility and Voluntary **Exclusion Lower Tier Covered** Transactions; AD–1049, Certification Regarding Drug-Free Workplace Requirements (Grants) Alternative I— For Grantees Other than Individuals; AD-1050, Certification Regarding Drug-Free Workplace Requirements (Grants) Alternative II—For Grantees Who Are Individuals; AD-1052, Certification Regarding Drug-Free Workplace State and State Agencies, Federal Fiscal Year.

Description of Respondents: Individuals or household; Business or other for-profit; Not-for-profit institutions; Federal Government; State, Local or Tribal Government.

Number of Respondents: 1.

Frequency of Responses: Reporting: One time.

Total Burden Hours: 1.

#### Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015-17671 Filed 7-17-15; 8:45 am]

BILLING CODE 3410-KS-P

#### **DEPARTMENT OF AGRICULTURE**

#### **Rural Utilities Service**

#### Information Collection Activity; Comment Request

**AGENCY:** Rural Utilities Service, USDA. **ACTION:** Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended), the United States Department of Agriculture (USDA) Rural Utilities Service (RUS) invites comments on the following information collections for which the RUS intends to request approval from the Office of Management and Budget (OMB).

**DATES:** Comments on this notice must be received by September 18, 2015.

#### FOR FURTHER INFORMATION CONTACT:

Thomas P. Dickson, Acting Director, Program Development and Regulatory Analysis, USDA Rural Utilities Service, 1400 Independence Avenue SW., STOP 1522, Room 5164, South Building, Washington, DC 20250–1522. Telephone: (202) 690–4492. Fax: (202) 720–8435 or email *Thomas.Dickson@wdc.usda.gov.* 

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. This notice identifies information collections that USDA Rural Development is submitting to OMB for extension.

Comments are invited on: (a) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology. Comments may be sent to Thomas P. Dickson, Acting Director, Program Development and Regulatory Analysis, USDA Rural

Utilities Service, 1400 Independence Avenue SW., STOP 1522, Room 5164, South Building, Washington, DC 20250– 1522. Telephone: (202) 690–4492. Fax: (202) 720–8435 or email Thomas.Dickson@wdc.usda.gov.

Title: Borrower Investments— Telecommunications Loan Program, 7 CFR 1744, Subpart E.

OMB Control Number: 0572-0098.

*Type of Request:* Extension of a currently approved collection.

Abstract: The Rural Economic Development Act of 1990, Title XXIII of the Farm Bill, Public Law 101-624, authorized qualified Rural Utilities Service (RUS) borrowers to make investments in rural development projects without the prior approval of the Agency's Administrator provided that such investments do not cause the borrower to exceed its allowable qualified investment level as determined in accordance with the procedures set forth in 7 CFR part 1744, subpart E. When a borrower exceeds these limits, the security for the Government's loans could be in jeopardy. However, in the interest of encouraging rural development, RUS will consider approving such investments that exceed a borrower's qualified investment level. This information collection covers those items that a borrower would need to submit to RUS for consideration of the borrower's request to make such an investment.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 1 hour per response.

*Respondents:* Not for profit institutions; business or other for-profit entities.

Estimated Number of Respondents: 2. Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 1 hour.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: July 10, 2015.

#### Brandon McBride,

Administrator, Rural Utilities Service. [FR Doc. 2015–17673 Filed 7–17–15; 8:45 am]

BILLING CODE 3410-15-P

#### **U.S. DEPARTMENT OF COMMERCE**

# Foreign-Trade Zones Board [B-45-2015]

Foreign-Trade Zone (FTZ) 277— Western Maricopa County, Arizona; Notification of Proposed Production Activity;The Cookson Company, Inc. (Rolling Steel Doors); Goodyear, Arizona

The Cookson Company, Inc. (Cookson) submitted a notification of proposed production activity to the FTZ Board for its facility in Goodyear, Arizona within FTZ 277. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on July 13, 2015.

The Cookson facility is located within Site 11 of FTZ 277. The facility is used for the assembly and production of rolling steel doors. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Cookson from customs duty payments on the foreign status components used in export production. On its domestic sales, Cookson would be able to choose the duty rates during customs entry procedures that apply to rolling steel doors (duty-free) for the foreign status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign status production equipment.

The components and materials sourced from abroad include: hand and roller steel chains; limit switches; single-phase AC electric motors/gear motors; multi-phase AC electric motors/gear motors; steel cranks; motor overload protectors; mounted and unmounted timers for door closure assemblies; power boards; transformers (40VA or greater); electro-mechanical alarm interfaces; fire door testing releases and converter mechanisms; steel door limits; contactors; battery backups; and, steel bolts (duty rate ranges from duty-free to 6.6%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is August 31, 2015.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the "Reading Room" section of the Board's Web site, which is accessible via www.trade.gov/ftz.

For further information, contact Elizabeth Whiteman at Elizabeth.Whiteman@trade.gov or (202) 482–0473.

Dated: July 15, 2015.

#### Andrew McGilvray,

Executive Secretary.

[FR Doc. 2015–17749 Filed 7–17–15; 8:45 am]

BILLING CODE 3510-DS-P

#### **DEPARTMENT OF COMMERCE**

#### **International Trade Administration**

[A-549-821]

Polyethylene Retail Carrier Bags From Thailand: Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

summary: The Department of Commerce (the Department) preliminarily determines that TPBI Public Company Limited (TPBI) is the successor-ininterest to Thai Plastic Bags Industries Company Limited (Thai Plastic Bags) for purposes of the antidumping duty order on polyethylene retail carrier bags (PRCBs) from Thailand and, as such, will be entitled to Thai Plastic Bags's exclusion from the antidumping duty order. We invite interested parties to comment on these preliminary results.

DATES: Effective: July 20, 2015.

#### FOR FURTHER INFORMATION CONTACT:

Thomas Schauer, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0410.

#### SUPPLEMENTARY INFORMATION:

#### **Background**

On June 18, 2004, the Department published the *Order* on PRCBs from Thailand. On August 12, 2010, the Department revoked the *Order* on PRCBs from Thailand with respect to PRCBs manufactured and exported by

Thai Plastic Bags as the result of a section 129 proceeding.<sup>2</sup>

On June 4, 2015, TPBI requested that the Department initiate an expedited changed circumstances review to confirm that TPBI is the successor-ininterest to Thai Plastic Bags for purposes of determining antidumping duty liabilities.<sup>3</sup> The petitioner supports TPBI's request for this changed circumstances review.<sup>4</sup> We received no comments opposing TPBI's request.

#### Scope of the Order

The merchandise subject to the order includes PRCBs from the Thailand. PRCBs are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 3923.21.0085. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description is dispositive.<sup>5</sup>

#### Methodology

In making a successor-in-interest determination, the Department typically examines several factors including, but not limited to, changes in: (1)
Management; (2) production facilities; (3) supplier relationships; and (4) customer base.<sup>6</sup> While no single factor or combination of factors will necessarily be dispositive, the Department generally will consider the new company to be the successor to the predecessor if the resulting operations of the successor are essentially the same as those of its predecessor.<sup>7</sup> Thus, if the

<sup>&</sup>lt;sup>1</sup> See Notice of Final Determination of Sales at Less Than Fair Value: Polyethylene Retail Carrier Bags from Thailand, 69 FR 34122 (June 18, 2004) (Order).

<sup>&</sup>lt;sup>2</sup> See Notice of Implementation of Determination Under Section 129 of the Uruguay Round Agreements Act and Partial Revocation of the Antidumping Duty Order on Polyethylene Retail Carrier Bags From Thailand, 75 FR 48940 (August 12, 2010).

<sup>&</sup>lt;sup>3</sup> See Letter from TPBI to the Department, "Polyethylene Retail Carrier Bags (PRCBs) from Thailand: Request for Expedited Changed Circumstances Review" (June 4, 2015) (CCR Request).

<sup>&</sup>lt;sup>4</sup> *Id.*, at Exhibit 9.

<sup>&</sup>lt;sup>5</sup> For a complete description of the Scope of the Order, see Memorandum to Paul Piquado, Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, entitled "Antidumping Duty Order on Polyethylene Retail Carrier Bags from Thailand: Decision Memorandum for the Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review Requested by TPBI Public Company Limited" dated concurrently with this notice and hereby adopted by this notice (Preliminary Decision Memorandum).

<sup>&</sup>lt;sup>6</sup> See, e.g., Certain Activated Carbon From the People's Republic of China: Notice of Initiation of Changed Circumstances Review, 74 FR 19934, 19935 (April 30, 2009).

<sup>&</sup>lt;sup>7</sup> See, e.g., Notice of Initiation of Antidumping Duty Changed Circumstances Review: Certain Forged Stainless Steel Flanges from India, 71 FR 327 (January 4, 2006).

record demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the predecessor company, the Department may assign the new company the cash deposit rate of its predecessor.<sup>8</sup> For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I of this notice.

# Initiation and Preliminary Results of the Changed Circumstances Review

Pursuant to section 751(b)(1) of the Act and 19 CFR 351.216(d), the Department will conduct a changed circumstances review (CCR) upon receipt of a request from an interested party or receipt of information concerning an antidumping duty order which shows changed circumstances sufficient to warrant a review of the order. Section 351.221(c)(3)(ii) of the Department's regulations permits the Department to combine the initiation and preliminary results of a CCR if the Department concludes that expedited action is warranted. In this instance, we have information on the record necessary to reach the preliminary results of CCR. As such, we find that expedited action is warranted. Accordingly, we have combined the preliminary results with the initiation.

We preliminarily determine that TPBI is the successor-in-interest to Thai Plastic Bags for the purposes of administering the *Order* and its revocation with respect to Thai Plastic Bags. The Preliminary Decision Memorandum provides a full description of the analysis underlying our conclusions.

#### **Public Comment**

Interested parties may submit case briefs no later than 30 days after the date of publication of this notice.<sup>9</sup> Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.<sup>10</sup> Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.<sup>11</sup> Pursuant to 19 CFR

351.310(c), interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce. All documents must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).12 An electronically-filed request must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time, within 30 days after the date of publication of this notice. 13 Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case

In accordance with 19 CFR 351.216(e), the Department intends to issue the final results of this changed circumstance review not later than 270 days after the date on which the review is initiated, or within 45 days if all parties agree to our preliminary finding.

#### **Notification to Interested Parties**

This notice is issued and published in accordance with sections 751(b) and 777(i)(1) of the Act, and 19 CFR 351.216 and 351.221(c)(3)(ii).

Dated: July 14, 2015.

#### Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

#### Appendix I

### List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary

II. Background

III. Scope of the Order

IV. Successor-in-Interest Analysis

- A. Analytical Framework
- B. Relevant Facts
- 1. Management
- 2. Production Facilities
- 3. Customer Base
- 4. Suppliers
- C. Analysis
- 1. Time Period
- 2. Successorship Analysis
- a. Management
- b. Production Facilities
- c. Customer Base
- d. Suppliers V. Recommendation

[FR Doc. 2015–17732 Filed 7–17–15; 8:45 am]

#### BILLING CODE 3510-DS-P

#### **DEPARTMENT OF COMMERCE**

### National Oceanic and Atmospheric Administration

RIN 0648-XE012

Fisheries of the South Atlantic; Southeast Data, Assessment and Review (SEDAR); Public Meetings

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of SEDAR 41 Data Workshop II for South Atlantic red snapper and gray triggerfish.

SUMMARY: The SEDAR 41 assessments of the South Atlantic stocks of red snapper (*Lutjanus campechanus*) and gray triggerfish (*Balistes capriscus*) will consist of: Data Workshops; an Assessment Workshop; and a Review Workshop. See SUPPLEMENTARY INFORMATION.

DATES: The SEDAR 41 Data Workshop II will be held on August 4, 2015, from 8:30 a.m. until 6 p.m.; August 5, 2015, from 8 a.m. until 6 p.m.; and August 6, 2015, from 8 a.m. until 1 p.m. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from, or completed prior to the time established by this notice. The Assessment Workshop and Review Workshop dates and times will publish in a subsequent issue in the Federal Register. See SUPPLEMENTARY INFORMATION.

ADDRESSES: The SEDAR 41 Data Workshop will be held at the Charleston Marriott, 170 Lockwood Boulevard, Charleston, SC 29403; phone: (843) 732– 3000.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator; phone: (843) 571–4366; email: julia.byrd@safmc.net.

supplementary information: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three step process including: (1) Data Workshop(s); (2) Assessment Process utilizing workshops and webinars; and

<sup>&</sup>lt;sup>8</sup> See, e.g., Fresh and Chilled Atlantic Salmon From Norway; Final Results of Changed Circumstances Antidumping Duty Administrative Review, 64 FR 9979, 9980 (March 1, 1999).

<sup>9</sup> See 19 CFR 351.309(c)(1)(ii).

<sup>10</sup> See 19 CFR 351.309(d).

<sup>11</sup> See 19 CFR 351.309(c)(2) and (d)(2).

<sup>&</sup>lt;sup>12</sup> ACCESS is available to registered users at http://access.trade.gov.

<sup>13</sup> See 19 CFR 351.310(c).

(3) Review Workshop. The product of the Data Workshop(s) is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, the Atlantic and Gulf States Marine Fisheries Commissions and NOAA Fisheries Southeast Regional Office and Southeast Fisheries Science Center. Participants include: data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and nongovernmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

An assessment data set and associated documentation will be developed during the Data Workshops. Participants will evaluate available data and select appropriate sources for providing information on life history characteristics, catch statistics, discard estimates, length and age composition, and fishery independent and fishery dependent measures of stock abundance, as specified in the Terms of Reference for the workshop. This workshop will build on the work and decisions made at the 2014 SEDAR 41 Data Workshop.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

#### **Special Accommodations**

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SEDAR office (see **ADDRESSES**) at least 10 business days prior to the meeting.

**Note:** The times and sequence specified in this agenda are subject to change.

Authority: 16 U.S.C. 1801 et seq.

Dated: July 15, 2015.

#### Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2015–17722 Filed 7–17–15; 8:45 am]

BILLING CODE 3510-22-P

#### **DEPARTMENT OF COMMERCE**

# National Oceanic and Atmospheric Administration

RIN 0648-XD983

#### Record of Decision for the Final NOAA Restoration Center Programmatic Environmental Impact Statement

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of availability of a Record of Decision.

SUMMARY: The NOAA National Marine Fisheries Service (NMFS) announces the availability of the Record of Decision (ROD) for the Final NOAA Restoration Center Programmatic Environmental Impact Statement. The NMFS Office of Habitat Conservation Director signed the ROD on July 20, 2015, which constitutes the agency's final decision.

ADDRESSES: Frederick C. Sutter, Director, Office of Habitat Conservation, National Oceanic and Atmospheric Administration, 1315 East-West Highway, Silver Spring, MD 20910.

#### FOR FURTHER INFORMATION CONTACT:

Melanie Gange, by mail at NOAA Restoration Center/FHC3, 1315 East-West Highway, Silver Spring, MD 20910; or by telephone at 301–427– 8664.

SUPPLEMENTARY INFORMATION: The PEIS evaluated broad issues and programmatic-level alternatives (compared to a document for a specific project or action) for future restoration activities to be carried out by NOAA. In addition to providing a programmatic analysis, NOAA intends to use this document to approve future site-specific actions, including grant actions, as long as the activity being proposed is within the range of alternatives and scope of potential environmental consequences described in the PEIS, and does not have significant adverse impacts. Any future site-specific restoration activities proposed by NOAA that are not within

the scope of alternatives or environmental consequences considered in the PEIS will require additional analysis under the National Environmental Policy Act (NEPA).

The ROD documents the decision by NOAA to select and implement the "Current Management" alternative as its preferred alternative. The alternative represents a comprehensive programmatic restoration approach that includes funding or conducting activities such as providing technical assistance; on-the-ground riverine and coastal habitat restoration activities (including but not limited to: Fish passage projects; channel, bank, and floodplain restoration; buffer area and watershed revegetation; salt marsh restoration; oyster restoration; marine debris removal; submerged aquatic vegetation planting; invasive species removal; and coral restoration); and habitat conservation transactions. Because this is a continuation of NOAA Restoration Center's (RC) on-going restoration programs with no change in management direction, it was also considered to be the "No Action" alternative.

The NOAA RC is not soliciting comments on the PEIS but will consider any comments submitted that would assist us in preparing future NEPA documents. An electronic copy of the PEIS is available at: <a href="http://www.restoration.noaa.gov/environmentalcompliance">http://www.restoration.noaa.gov/environmentalcompliance</a>. Electronic correspondence regarding it can be submitted to <a href="mailto:rc.compliance@noaa.gov">rc.compliance@noaa.gov</a>. Otherwise, please submit any written comments via U.S. mail to the responsible official named in the ADDRESSES section.

Dated: July 15, 2015.

#### Frederick C. Sutter,

Director, Office of Habitat Conservation, National Marine Fisheries Service.

[FR Doc. 2015-17739 Filed 7-17-15; 8:45 am]

BILLING CODE 3510-22-P

#### **DEPARTMENT OF COMMERCE**

# National Oceanic and Atmospheric Administration

RIN 0648-XE033

# North Pacific Fishery Management Council; Public Meeting

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of a public meeting.

**SUMMARY:** The North Pacific Fishery Management Council's (Council)

Ecosystem Committee will meet in Juneau, AK.

**DATES:** The meeting will be held August 6–7, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Ted Stevens Marine Research Institute, Auke Bay Laboratories, 17109 Pt. Lena Loop Road, Juneau, AK 99801.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

#### FOR FURTHER INFORMATION CONTACT:

Steve MacLean, Council staff; phone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The purpose of the Ecosystem Committee is to review progress on development of a strawman Fishery Ecosystem Plan (FEP) Module, and development of a discussion paper planned for presentation to the Council in December, 2015. The Committee will also discuss scheduling for future meetings. The Agenda is subject to change, and the latest version will be posted at <a href="http://www.npfmc.org/">http://www.npfmc.org/</a>.

#### **Special Accommodations**

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: July 15, 2015.

#### Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 2015–17723 Filed 7–17–15; 8:45 am]

BILLING CODE 3510-22-P

#### **DEPARTMENT OF COMMERCE**

### National Oceanic and Atmospheric Administration

RIN 0648-XE019

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Crab Rationalization Cost Recovery Program

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notification of fee percentage.

SUMMARY: NMFS publishes notification of a 1.48 percent fee for cost recovery under the Bering Sea and Aleutian Islands Crab Rationalization Program. This action is intended to provide holders of crab allocations with the fee percentage for the 2015/2016 crab

fishing year so they can calculate the required payment for cost recovery fees that must be submitted by July 31, 2016.

**DATES:** The Crab Rationalization Program Registered Crab Receiver permit holder is responsible for submitting the fee liability payment to NMFS on or before July 31, 2016.

FOR FURTHER INFORMATION CONTACT: Keeley Kent, 907-586-7228.

#### SUPPLEMENTARY INFORMATION:

#### **Background**

NMFS Alaska Region administers the Bering Sea and Aleutian Islands Crab Rationalization Program (Program) in the North Pacific. Fishing under the Program began on August 15, 2005. Regulations implementing the Program can be found at 50 CFR part 680.

The Program is a limited access system authorized by section 313(j) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Program includes a cost recovery provision to collect fees to recover the actual costs directly related to the management, data collection, and enforcement of the Program. NMFS developed the cost recovery provision to conform to statutory requirements and to partially reimburse the agency for the actual costs directly related to the management, data collection, and enforcement of the Program. Section 313(j) of the Magnuson-Stevens Act provided supplementary authority to section 304(d)(2)(A) and additional detail for cost recovery provisions specific to the Program. The cost recovery provision allows collection of 133 percent of the actual management, data collection, and enforcement costs up to 3 percent of the ex-vessel value of crab harvested under the Program. Additionally, section 313(j) requires the harvesting and processing sectors to each pay half the cost recovery fees. Catcher/processor quota shareholders are required to pay the full fee percentage for crab processed at sea.

A crab allocation holder generally incurs a cost recovery fee liability for every pound of crab landed. The crab allocations include Individual Fishing Quota, Crew Individual Fishing Quota, Individual Processing Quota, Community Development Quota, and the Adak community allocation. The Registered Crab Receiver (RCR) permit holder must collect the fee liability from the crab allocation holder who is landing crab. Additionally, the RCR permit holder must collect his or her own fee liability for all crab delivered to the RCR. The RCR permit holder is responsible for submitting this payment

to NMFS on or before July 31, in the year following the crab fishing year in which landings of crab were made.

The dollar amount of the fee due is determined by multiplying the fee percentage (not to exceed 3 percent) by the ex-vessel value of crab debited from the allocation. Specific details on the Program's cost recovery provision may be found in the implementing regulations at 50 CFR 680.44.

#### Fee Percentage

Each year, NMFS calculates and publishes in the Federal Register the fee percentage according to the factors and methodology described in Federal regulations at § 680.44(c)(2). The formula for determining the fee percentage is the "direct program costs" divided by "value of the fishery," where "direct program costs" are the direct program costs for the Program for the previous fiscal year, and "value of the fishery" is the ex-vessel value of the catch subject to the crab cost recovery fee liability for the current year. Fee collections for any given year may be less than, or greater than, the actual costs and fishery value for that year, because, by regulation, the fee percentage is established in the first quarter of a crab fishery year based on the fishery value and the costs of the prior year.

Based upon the fee percentage formula described above, the estimated percentage of costs to value for the 2014/2015 fishery was 1.48 percent. Therefore, the fee percentage will be 1.48 percent for the 2015/2016 crab fishing year. This is an increase of 0.83 percent from the 2013/2014 fee percentage of 0.65 percent (79 FR 44403, July 31, 2014). The change in the fee percentage from 2013/2014 to 2014/ 2015 is due to an increase in NMFS management costs. These additional costs were necessary to maintain and upgrade NMFS' permitting systems and the Internet-based crab landings system used for the program. The value of crab harvested under the Program also increased from 2013/2014 to 2014/2015 by \$29 million. This increase in value of the fishery offset some of the management cost increases and so limited the change in the fee percentage between 2013/2014 and 2014/2015.

**Authority:** 16 U.S.C. 1862; Pub. L. 109–241; Pub. L. 109–479.

Dated: July 14, 2015.

#### Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2015–17639 Filed 7–17–15; 8:45 am]

BILLING CODE 3510-22-P

#### **DEPARTMENT OF COMMERCE**

#### National Oceanic and Atmospheric Administration

RIN 0648-XE058

Fisheries of the South Atlantic; South Atlantic Fishery Management Council; Public Hearings

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Notice of public hearings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold public hearings in North Carolina, South Carolina and Florida and a Question and Answer Webinar for Regulatory Amendment 16 to the Snapper Grouper Fishery Management Plan for the South Atlantic. The Council will also hold public hearings in North Carolina, South Carolina, Georgia, and Florida and a Question and Answer Webinar for Amendment 36 to the Snapper Grouper Fishery Management Plan for the South Atlantic. See

#### SUPPLEMENTARY INFORMATION.

**DATES:** The public hearings will be held between August 10 and August 25, 2015. There will be a question and answer webinar on August 3 and August 5, 2015. Please see **SUPPLEMENTARY INFORMATION** for specific details.

ADDRESSES: The hearings for Snapper Grouper Regulatory Amendment 16 will be held in Little River, SC, Jacksonville, NC, Ormond Beach, FL. The hearings for Snapper Grouper Amendment 36 will be held in North Charleston, SC, Murrells Inlet, SC, Morehead City, NC, Brunswick, GA and Daytona Beach, FL, with an additional hearing being held via webinar. Please see SUPPLEMENTARY INFORMATION for specific locations.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405; phone: (843) 571–4366 or toll free (866) SAFMC–10; fax: (843) 769–4520; email: kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: The hearings on Snapper Grouper Regulatory Amendment 16 will take place August 11 (Little River, SC), August 12 (Jacksonville, NC), and August 17 (Ormond Beach, FL). The Question and Answer Webinar for Snapper Grouper Regulatory Amendment 16 will be on Monday, August 3, 2015.

The public hearings for Snapper Grouper Amendment 36 will take place August 10 (N. Charleston, SC), August 12 (Murrells Inlet, SC), August 13 (Morehead City, NC), August 18 (Webinar hearing), August 24 (Brunswick, GA), and August 25 (Daytona Beach, FL). The Question and Answer Webinar for Snapper Grouper Amendment 36 will be on Monday, August 5, 2015.

Snapper Grouper Regulatory Amendment 16 (black sea bass pots)

The Q&A Session for Regulatory Amendment 16 will begin at 6 p.m. on Monday, August 3, 2015. Registration is required and registration information will be posted on the Council's Web site at www.safmc.net as it becomes available.

Public Hearings for Snapper Grouper Regulatory Amendment 16 begin at 4 p.m. in the following locations:

1. August 11, 2015: Holiday Inn Express, 722 Highway 17, Little River, SC 29566; phone: (843) 281–9400.

2. August 12, 2015: Comfort Suites, 130 Workshop Lane, Jacksonville, NC 28546; phone: (910) 346–8900.

3. August 17, 2015: Hull's Seafood Market/Restaurant, 111 West Granada Blvd., Ormond Beach, FL 32174; phone: (386) 677–1511.

Snapper Grouper Amendment 36 (Spawning SMZs)

The Q&A Session for Snapper Grouper Amendment 36 will begin at 6 p.m. on Monday, August 5, 2015. Registration is required and registration information will be posted on the Council's Web site at <a href="https://www.safmc.net">www.safmc.net</a> as is becomes available.

Public Hearings for Snapper Grouper Amendment 36 begin at 4 p.m. in the following locations:

- 1. August 10, 2015: Hilton Garden Inn, 5265 International Blvd., N. Charleston, SC 29418; phone: (843) 308– 9330.
- 2. August 12, 2015: Murrells Inlet Community Center, 4462 Murrells Inlet Road, Murrells Inlet, SC 29576; phone: (843) 651–7373.
- 3. August 13, 2015: NC Division of Marine Fisheries, Central District Office, 5285 Highway 70 West, Morehead City, NC 28557; phone: (252) 726–7021.
- 4. August 18, 2015: Public Hearing via webinar—registration for the webinar is required. Information regarding registration will be posted on the Council's Web site at www.safmc.net.
- 5. August 24, 2015: Georgia Dept. of Natural Resources, Coastal Resources Division, One Conservation Way, Brunswick, GA 31520–8687; phone: (912) 264–7218.
- 6. August 25, 2015: Hilton Garden Inn—Daytona Beach Airport, 189

Midway Ave., Daytona Beach, FL 32114; phone: (386) 944–4000.

Snapper Grouper Regulatory Amendment 16

Snapper Grouper Regulatory Amendment 16 has two actions. The first action is to consider options for opening the commercial South Atlantic black sea bass pot fishery from November 1 through April 30 while still providing protection for ESA listed whales during that period. The second action has alternatives that would require modifications to black sea bass pot gear such as reducing buoy line and weak link strength, as well as require markings that would identify gear as being specific to the South Atlantic black sea bass pot fishery. Background information regarding Snapper Grouper Regulatory Amendment 16, including a public hearing draft of the document, a document summary, and a PowerPoint presentation will be posted to the South Atlantic Fishery Management Council's Web site www.safmc.net no later than 5 p.m. on July 30, 2015. In addition to making public comments in person, interested persons can make comments via email or U.S. mail no later than 5 p.m. on August 21, 2015. Email comments may be sent to: Mike.Collins@ safmc.net. Please include the words "Regulatory Amendment 16" in the subject line of the email. Comments submitted by U.S. mail should be sent to: Robert K. Mahood, Executive Director, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

Snapper Grouper Amendment 36

Snapper Grouper Amendment 36 has nine actions. Action 1 modifies the Special Management Zone (SMZ) procedures to include protection of natural bottom; Action 2 modifies the framework procedure to allow modification of and/or additional Spawning SMZs; Actions 3–7 includes alternatives to establish Spawning SMZs off NC, SC, GA, and FL where fishing for snapper grouper species would be prohibited, however, fishing for other species (e.g., billfish, tunas, mackerels) would be allowed; Action 8 would establish transit and anchoring provisions; and Action 9 would add a "sunset provision" for Spawning SMZs after 10 years if not reauthorized. Background information regarding Snapper Grouper Amendment 36, including a public hearing draft of the document, a document summary, and a PowerPoint presentation will be posted to the Council's Web site (www.safmc.net) no later than 5 p.m. on

July 30, 2015. Written comments will also be accepted via email or U.S. mail until 5 p.m. on August 31, 2015. Email comments to: Mike.Collins@safmc.net. Please include the words "Amendment 36" in the subject line of the email. Comments submitted by U.S. mail should be sent to: Robert K. Mahood, Executive Director, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

#### **Special Accommodations**

These hearings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see ADDRESSES) 3 days prior to the meeting.

**Note:** The times and sequence specified in this agenda are subject to change.

Dated: July 14, 2015.

#### Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2015–17650 Filed 7–17–15; 8:45 am]

BILLING CODE 3510-22-P

#### **DEPARTMENT OF DEFENSE**

#### Office of the Secretary

#### Charter Renewal of Department of Defense Federal Advisory Committees

**AGENCY:** Department of Defense. **ACTION:** Amendment of Federal Advisory Committee.

**SUMMARY:** The Department of Defense is publishing this notice to announce that it is amending the charter for the Defense Business Board ("the Board").

**FOR FURTHER INFORMATION CONTACT:** Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

**SUPPLEMENTARY INFORMATION:** This committee's charter is being amended in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended) and 41 CFR 102–3.50(d).

The Board is a discretionary Federal advisory committee that provides the Secretary of Defense and the Deputy Secretary of Defense with independent advice and recommendations on critical matters concerning the Department of Defense (DoD). The Board shall examine and advise on overall DoD management and governance from a private sector perspective.

The DoD, through the Office of the Deputy Chief Management Officer (DCMO), shall provide support for the performance of the Board's functions

and shall ensure compliance with the requirements of the FACA, the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended) ("the Sunshine Act"), governing Federal statutes and regulations, and established DoD policies and procedures.

The Board shall be composed of no more than 35 members. The members must possess the following: (a) A proven track record of sound judgment in leading or governing large, complex private sector corporations or organizations and (b) a wealth of toplevel, global business experience in the areas of executive management, corporate governance, audit and finance, human resources, economics, technology, or healthcare. The Board members will be appointed by the Secretary of Defense or the Deputy Secretary of Defense for a term of service of one-to-four years and will be renewed on an annual basis in accordance with DoD policies and procedures. Members of the Board who are not full-time or permanent part-time Federal officers or employees will be appointed as experts or consultants pursuant to 5 U.S.C. 3109 to serve as special government employee (SGE) members. Members of the Board who are full-time or permanent part-time Federal officers or employees will be appointed pursuant to 41 CFR 102-3.130(a) to serve as regular government employee (RGE) members. All members of the Board are appointed to provide advice on the basis of their best judgment without representing any particular point of view and in a manner that is free from conflict of interest.

Consistent with Deputy Secretary of Defense policy, the DCMO may appoint the Board chair or vice chairs from among the Secretary of Defense approved Board membership and, in doing so, the DCMO shall determine the term of service for the Board chair and/or chairs, which shall not exceed the member's approved term of service.

All Board members will be reimbursed for travel and per diem as it pertains to official business of the Board. Board members will serve without compensation. No member, unless authorized by the Secretary of Defense or the Deputy Secretary of Defense, may serve more than two consecutive terms of service on the Board, to include its subcommittees, or serve on more than two DoD federal advisory committees at one time.

The Secretary of Defense or the Deputy Secretary of Defense, according to DoD policies and procedures pertaining to inviting or appointing individuals to serve on advisory committees, may invite the chairs of the

Defense Policy Board and the Defense Science Board to serve as non-voting exofficio SGE members of the Board and the Director of the Office of Management and Budget and the Comptroller General of the United States to serve as non-voting ex-officio RGE members of the Board. The nonvoting ex-officio SGE members may speak to the Board membership only on those topics governed by their respective advisory boards provided the information has been voted on by their membership and is available to the general public. They do not represent their respective advisory boards. These non-voting ex-officio SGE and RGE members, when invited by the Secretary of Defense, will not count toward the Board's total membership and may not participate in the Board's deliberations.

The Director of Administration, Office of the DCMO, on behalf of the Secretary of Defense, the Deputy Secretary of Defense, and the DCMO and pursuant to DoD policies and procedures, may appoint, as deemed necessary, nonvoting subject matter experts (SMEs) to assist the Board or its subcommittees on an ad hoc basis. These non-voting SMEs are not members of the Board or its subcommittees and will not engage or participate in any deliberations by the Board or its subcommittees. These nonvoting SMEs, if not full-time or permanent part-time Federal government officers or employees, will be appointed pursuant to 5 U.S.C. 3109 on an intermittent basis to address specific issues under consideration by the Board.

DoD, when necessary and consistent with the Board's mission and DoD policies and procedures, may establish subcommittees, task forces, or working groups to support the Board. Establishment of subcommittees will be based upon a written determination, to include terms of reference, by the Secretary of Defense or the Deputy Secretary of Defense. Such subcommittees shall not work independently of the Board and shall report all their recommendations and advice solely to the Board for full deliberation and discussion. Subcommittees, task forces, or working groups have no authority to make decisions and recommendations, verbally or in writing, on behalf of the Board. No subcommittee or any of its members can update or report, verbally or in writing, directly to the DoD or to any Federal officer or employee.

The Secretary of Defense or the Deputy Secretary of Defense shall appoint subcommittee members even if the member in question is already a member of the Board. Subcommittee members, with the approval of the Secretary of Defense, may serve a term of one-to-four years, subject to annual renewals of their appointment; however, no individual appointed to any subcommittee of the Board shall serve more than a total of two consecutive terms of service on the Board including any subcommittees unless otherwise authorized by the Secretary of Defense or the Deputy Secretary of Defense.

Subcommittee members, if not full-time or permanent part-time Federal officers or employees, will be appointed as experts or consultants pursuant to 5 U.S.C. 3109 to serve as SGE members. Those subcommittee members who are full-time or permanent part-time Federal officers or employees will be appointed pursuant to 41 CFR 102–3.130(a) to serve as RGE employees. With the exception reimbursement of official travel and per diem related to the Board or its subcommittees, subcommittee members shall serve without compensation.

Each subcommittee member is appointed to provide advice on behalf of the Government on the basis of his or her best judgment without representing any particular point of view and in a manner that is free from conflict of interest.

Consistent with Deputy Secretary of Defense policy, the DCMO may appoint the subcommittee chair or chairs from among the Secretary of Defense approved subcommittee membership and, in doing so, the DCMO shall determine the term of service for the subcommittee chair or chairs, which shall not exceed the member's approved term of service.

All subcommittees operate under the provisions of FACA, the Sunshine Act, governing Federal statutes and regulations, and established DoD policies and procedures.

The Board's Designated Federal Officer (DFO) must be a full-time or permanent part-time DoD employee, designated in accordance with established DoD policies and

procedures.

The Board's DFO is required to attend all meetings of the Board and its subcommittees for the entire duration of each and every meeting. However, in the absence of the Board's DFO, a properly approved Alternate DFO, duly appointed to the Board according to DoD policies and procedures, must attend the entire duration of all meetings of the Board or its subcommittees.

The DFO, or the Alternate DFO, shall call all of the Board and its subcommittees meetings; prepare and approve all meeting agendas; and adjourn any meeting when the DFO, or the Alternate DFO, determines adjournment to be in the public interest or required by governing regulations or DoD policies and procedures.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written statements to Board membership about the Board's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Board.

All written statements shall be submitted to the DFO for the Board, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Board's DFO can be obtained from the GSA's FACA Database—http://www.facadatabase.gov/.

The DFO, pursuant to 41 CFR 102–3.150, will announce planned meetings of the Board. The DFO, at that time, may provide additional guidance on the submission of written statements that are in response to the stated agenda for the planned meeting in question.

Dated: July 15, 2015.

#### Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–17696 Filed 7–17–15; 8:45 am]

BILLING CODE 5001-06-P

#### **DEPARTMENT OF DEFENSE**

#### Office of the Secretary

Judicial Proceedings Since Fiscal Year 2012 Amendments Panel (Judicial Proceedings Panel); Notice of Federal Advisory Committee Meeting

**AGENCY:** Department of Defense. **ACTION:** Notice of meeting.

**SUMMARY:** The Department of Defense is publishing this notice to announce the following Federal Advisory Committee meeting of the Judicial Proceedings since Fiscal Year 2012 Amendments Panel ("the Judicial Proceedings Panel" or "the Panel"). The meeting is open to the public.

**DATES:** A meeting of the Judicial Proceedings Panel will be held on Thursday, August 6, 2015. The Public Session will begin at 10:00 a.m. and end at 5:00 p.m.

**ADDRESSES:** The George Washington University, School of Law, Faculty Conference Center, 2000 H St. NW., Washington, DC 20052.

FOR FURTHER INFORMATION CONTACT: Ms. Julie Carson, Judicial Proceedings Panel, One Liberty Center, 875 N. Randolph

Street, Suite 150, Arlington, VA 22203. Email: whs.pentagon.em.mbx.judicial-panel@mail.mil. Phone: (703) 693–3849. Web site: http://jpp.whs.mil.

**SUPPLEMENTARY INFORMATION:** This public meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: In section 576(a)(2) of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239), as amended, Congress tasked the Judicial Proceedings Panel to conduct an independent review and assessment of judicial proceedings conducted under the Uniform Code of Military Justice (UCMJ) involving adult sexual assault and related offenses since the amendments made to the UCMJ by section 541 of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112-81; 125 Stat. 1404), for the purpose of developing recommendations for improvements to such proceedings. At this meeting, the Panel will review plans to address current and pending topics and deliberate on issues relating to restitution and compensation for sexual assault victims and retaliation against individuals who report incidents of sexual assault within the military. The Panel is interested in written and oral comments from the public, including non-governmental organizations, relevant to these issues or any of the Panel's tasks.

#### Agenda

- 8:30-9:00 Administrative Session (41 CFR 102-3.160, not subject to notice & open meeting requirements)
- 9:00-10:00 Panel Discussion
   Regarding Current and Pending
   Topics: Restitution and
   Compensation, Retaliation against
   Sexual Assault Victims, Trends and
   Statistics of Sexual Assault Crimes
   Response, and Article 120 of the
   UCMJ (Public meeting begins)
- 10:00–12:30 Deliberations: Restitution and Compensation for Sexual Assault Victims
- 12:30-1:00 Lunch
- 1:00–4:30 Deliberations: Retaliation Against Victims of Sexual Assault Crimes
- 4:30-4:45 Break
- 4:45–5:00 Public Comment

Availability of Materials for the Meeting: A copy of the August 6, 2015 meeting agenda or any updates or changes to the agenda, to include individual speakers not identified at the time of this notice, as well as other materials presented related to the meeting, may be obtained at the meeting or from the Panel's Web site at <a href="http://jpp.whs.mil">http://jpp.whs.mil</a>.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is limited and is on a first-come basis.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Ms. Julie Carson at whs.pentagon.em.mbx.judicial-panel@mail.mil at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Procedures for Providing Public Comments: Pursuant to 41 CFR 102-3.140 and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written comments to the Panel about its mission and topics pertaining to this public session. Written comments must be received by Ms. Julie Carson at least five (5) business days prior to the meeting date so that they may be made available to the Judicial Proceedings Panel for their consideration prior to the meeting. Written comments should be submitted via email to Ms. Carson at whs.pentagon.em.mbx.judicial-panel@ *mail.mil* in the following formats: Adobe Acrobat or Microsoft Word. Please note that since the Judicial Proceedings Panel operates under the provisions of the Federal Advisory Committee Act, as amended, all written comments will be treated as public documents and will be made available for public inspection. If members of the public are interested in making an oral statement, a written statement must be submitted along with a request to provide an oral statement. Oral presentations by members of the public will be permitted between 4:45 p.m. and 5:00 p.m. on August 6, 2015 in front of the JPP members. The number of oral presentations to be made will depend on the number of requests received from members of the public on a first-come basis. After reviewing the requests for oral presentation, the Chairperson and the Designated Federal Officer will, having determined the statement to be relevant to the Panel's mission, allot five minutes to persons desiring to make an oral presentation.

Committee's Designated Federal Officer: The Panel's Designated Federal Officer is Ms. Maria Fried, Judicial Proceedings Panel, 1600 Defense Pentagon, Room 3B747, Washington, DC 20301–1600.

Dated: July 15, 2015.

#### Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015-17720 Filed 7-17-15; 8:45 am]

BILLING CODE 5001-06-P

#### **DEPARTMENT OF EDUCATION**

List of Correspondence From April 1, 2014 Through June 30, 2014 and July 1, 2014 Through September 30, 2014

**AGENCY:** Office of Special Education and Rehabilitative Services, Department of Education.

**ACTION:** Notice.

SUMMARY: The Secretary is publishing the following list of correspondence from the U.S. Department of Education (Department) to individuals during the second and third quarters of 2014. The correspondence describes the Department's interpretations of the Individuals with Disabilities Education Act (IDEA) or the regulations that implement the IDEA. This list and the letters or other documents described in this list, with personally identifiable information redacted, as appropriate, can be found at: <a href="https://www2.ed.gov/policy/speced/guid/idea/index.html">www2.ed.gov/policy/speced/guid/idea/index.html</a>.

# **FOR FURTHER INFORMATION CONTACT:** Jessica Spataro or Mary Louise Dirrigl. Telephone: (202) 245–7605.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), you can call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

Individuals with disabilities can obtain a copy of this list and the letters or other documents described in this list in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting Jessica Spataro or Mary Louise Dirrigl at (202) 245–7605.

SUPPLEMENTARY INFORMATION: The following list identifies correspondence from the Department issued from April 1, 2014 through June 30, 2014 and July 1, 2014 through September 30, 2014. Under section 607(f) of the IDEA, the Secretary is required to publish this list quarterly in the Federal Register. The list includes those letters that contain interpretations of the requirements of the IDEA and its implementing regulations, as well as letters and other documents that the Department believes will assist the public in understanding the requirements of the law. The list identifies the date and topic of each letter and provides summary

information, as appropriate. To protect the privacy interests of the individual or individuals involved, personally identifiable information has been redacted, as appropriate.

#### Part B—Assistance for Education of All Children With Disabilities

Section 611—Authorization; Allotment; Use of Funds; Authorization of Appropriations; and Section 619— Preschool Grants

Topic Addressed: Subgrants to Local Educational Agencies

O Letter dated June 11, 2014, to Chief State School Officers, providing guidance on how recent changes to the National School Lunch Program could affect the manner in which State educational agencies allocate Part B of IDEA funds to local educational agencies (LEAs) based on their relative numbers of children living in poverty.

Section 612—State Eligibility

Topic Addressed: Children in Private Schools

O Letter dated September 29, 2014, to Teach NYS President Sam Sutton and consultant David Rubel, regarding whether certain inclusive models could be used in the delivery of special education and related services to children with disabilities enrolled by their parents in private schools.

Section 615—Procedural Safeguards

Topic Addressed: Impartial Due Process Hearings

O Letter dated June 2, 2014, to Pennsylvania Attorney Mark W. Voigt, regarding a State's timeline for an LEA to implement a final due process hearing decision.

### Part C—Infants and Toddlers With Disabilities

Section 640—Payor of Last Resort

Topic Addressed: System of Payments

O Letter dated July 10, 2014, to Texas Department of Assistive and Rehabilitative Services Part C Coordinator Kim Wedel, clarifying how the system of payment requirements can be implemented while using a parent's or child's public and private insurance or benefits as a funding source for services under Part C of IDEA.

Other Letters That Do Not Interpret Idea But May Be of Interest to Readers

O Dear Colleague Letter from the Office for Civil Rights dated May 14, 2014, regarding the applicability to public charter schools of Federal civil rights laws, regulations, and guidance.

Electronic Access to This Document: The official version of this document is the document published in the **Federal** Register. Free Internet access to the official edition of the Federal Register and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the Federal Register, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: July 15, 2015.

#### Michael K. Yudin,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2015-17766 Filed 7-17-15; 8:45 am]

BILLING CODE 4000-01-P

#### **DEPARTMENT OF ENERGY**

#### Federal Energy Regulatory Commission

[Docket No. EL15-67-000]

#### Linden VFT, LLC v. PJM Interconnection, L.L.C.; Notice of Amended Complaint

Take notice that on July 10, 2015, pursuant to sections 206 and 306 of the Federal Power Act, 16 U.S.C. 824(e) and 825(e) and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, Linden VFT, LLC (Complainant), filed an amended complaint against PJM Interconnection, L.L.C. (PJM or Respondent), alleging that the Respondent's proposed cost allocations for projects resulting from PJM's 2013 Regional Transmission Expansion Plan, including Public Service Electric and Gas Company upgrades, are unjust, unreasonable, unduly discriminatory, and preferential, as more fully explained in the complaint.

The Complainant certifies that copies of the complaint were served on the contacts for the Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of

the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at http://www.ferc.gov. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at http://www.ferc.gov, using the "eLibrary" link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208–3676 (toll free). For TTY, call (202) 502-8659.

Comment Date: 5:00 p.m. Eastern Time on July 30, 2015.

Dated: July 14, 2015.

#### Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-17695 Filed 7-17-15; 8:45 am]

BILLING CODE 6717-01-P

#### **DEPARTMENT OF ENERGY**

#### Federal Energy Regulatory Commission

#### Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11-3576-012; ER11-3401-011.

Applicants: Golden Spread Electric Cooperative, Inc., Golden Spread Panhandle Wind Ranch, LLC.

Description: Notice of Non-material Change in Status of Golden Spread Electric Cooperative, Inc.

Filed Date: 7/13/15 Accession Number: 20150713-5221. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER13-1947-001. Applicants: PJM Interconnection,

Description: Compliance filing: Designation of Filing Party assoc to Compliance Filing in Docket No. ER13-1947 to be effective N/A.

Filed Date: 7/14/15.

Accession Number: 20150714-5095. Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-1196-003. Applicants: Nevada Power Company, Sierra Pacific Power Company.

Description: Compliance Filing with no tariff revisions of Nevada Power Company, et al.

Filed Date: 7/13/15.

Accession Number: 20150713-5227. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15-2200-000. Applicants: PJM Interconnection,

L.L.C.

Description: Compliance filing: Compliance Filing per 5/14/2015 Order in Docket No. ER13-1947-000 to be effective 1/1/2014.

Filed Date: 7/14/15.

Accession Number: 20150714-5087. Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-2201-000. Applicants: Alabama Power

Company.

Description: Section 205(d) Rate Filing: Wheeler Solar (McRae Solar) SGIA Filing to be effective 6/29/2015.

Filed Date: 7/14/15.

Accession Number: 20150714-5107. Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-2202-000. Applicants: Alabama Power Company.

Description: Section 205(d) Rate Filing: Wheeler Solar (Wheeler Solar) SGIA Filing to be effective 6/29/2015. Filed Date: 7/14/15.

Accession Number: 20150714-5108. Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-2203-000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Section 205(d) Rate Filing: 2015-07-14 SA 2819 Certificate of Concurrence ComEd-Ameren TIA to be effective 7/13/2015.

Filed Date: 7/14/15.

Accession Number: 20150714-5127. Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-2204-000. Applicants: California Independent

System Operator Corporation. Description: Section 205(d) Rate Filing: 2015-07-14 Pricing

Enhancements-ETC-TOR Self-Schedules to be effective 9/15/2015.

Filed Date: 7/14/15.

Accession Number: 20150714-5135. Comments Due: 5 p.m. ET 8/4/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: http://www.ferc.gov/docs-filing/efiling/filing-req.pdf. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 14, 2015.

#### Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-17694 Filed 7-17-15; 8:45 am]

BILLING CODE 6717-01-P

#### **DEPARTMENT OF ENERGY**

#### Federal Energy Regulatory Commission

#### **Combined Notice of Filings #2**

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC15–98–000. Applicants: Union Power Partners, L.P., Entergy Arkansas, Inc., Entergy Gulf States Louisiana, L.L.C., Entergy Texas, Inc.

Description: Response to May 28, 2015 letter requesting additional information of Entergy Services, Inc. on behalf of Union Power Partners, L.P., et al.

Filed Date: 6/30/15.

 $\begin{array}{l} Accession\ Number: 20150630-5458.\\ Comments\ Due: 5\ p.m.\ ET\ 8/14/15. \end{array}$ 

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–1942–001. Applicants: New York Independent System Operator, Inc.

Description: Compliance filing: NYISO Compliance Order 1000 Interregional Tariff Revisions to be effective 1/1/2014.

Filed Date: 7/13/15.

Accession Number: 20150713–5137. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER13–1946–001. Applicants: New York Independent System Operator, Inc.

Description: Compliance filing: Compliance Filing Order No. 1000 Designation of Filing Party to be effective 7/13/2015.

Filed Date: 7/13/15.

Accession Number: 20150713–5140.
Comments Due: 5 p.m. ET 8/3/15.
Docket Numbers: ER13–1957–001.
Applicants: ISO New England Inc.
Description: Compliance filing:
Second Interregional Compliance Filing
Protocol Agreement to be effective 7/13/2015.

Filed Date: 7/13/15.

Accession Number: 20150713–5106. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER13–1960–001. Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: Compliance filing: Second Interregional Compliance Filing Tariff Revisions to be effective 1/1/2014. Filed Date: 7/13/15.

Accession Number: 20150713–5139. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER14–1661–001. Applicants: MidAmerican Central California Transco, LLC.

Description: Compliance filing: Settlement Compliance Filing to be effective 6/5/2014.

Filed Date: 7/13/15.

Accession Number: 20150713–5101. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15–535–002. Applicants: Nevada Power Company. Description: Compliance filing: OATT

Order No. 676–H Compliance Filing 07.13.15 to be effective 5/15/2015. *Filed Date:* 7/13/15.

Accession Number: 20150713–5138. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15–2184–000. Applicants: Southwest Power Pool,

Description: Section 205(d) Rate Filing: 3055 Associated Electric Cooperative, Inc. NITSA NOA to be effective 6/1/2015.

Filed Date: 7/13/15.

Accession Number: 20150713–5053. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15–2185–000. Applicants: PJM Interconnection,

L.L.C.

Description: Section 205(d) Rate Filing: Service Agreement No. 4210; Queue No. Z2–090 to be effective 4/8/ 2015.

Filed Date: 7/13/15.

Accession Number: 20150713–5054. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15–2186–000. Applicants: Midcontinent

Description: Section 205(d) Rate Filing: 2015–07–13 RSG Interchange Schedules Emergency Directives to be effective 9/11/2015.

Independent System Operator, Inc.

Filed Date: 7/13/15.

Accession Number: 20150713–5125. Comments Due: 5 p.m. ET 8/3/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: http://www.ferc.gov/docs-filing/efiling/filing-req.pdf. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 13, 2015.

#### Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–17692 Filed 7–17–15; 8:45 am]

BILLING CODE 6717-01-P

#### **DEPARTMENT OF ENERGY**

### Federal Energy Regulatory Commission

#### Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC15–167–000. Applicants: Sky River LLC, Sky River Asset Holdings, LLC, Sagebrush, a California partnership, Sagebrush Partner Fifteen, Inc.

Description: Application of Sky River LLC, et al. for Authorization Under Section 203 of the Federal Power Act and Request for Expedited Action.

Filed Date: 7/13/15.

Accession Number: 20150713–5216. Comments Due: 5 p.m. ET 8/3/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3168–013; ER15–356–003; ER15–357–003; ER12– 2570–009; ER13–618–008.

Applicants: ArcLight Energy Marketing, LLC, Chief Conemaugh Power, LLC, Chief Keystone Power, LLC, Panther Creek Power Operating, LLC, Westwood Generation, LLC.

Description: Notice of Non-Material Change in Status of ArcLight Energy Marketing, LLC, et al.

Filed Date: 7/13/15. Accession Number: 20150713-5212. Comments Due: 5 p.m. ET 8/3/15. Docket Numbers: ER14-2871-005: ER10-3243-007; ER10-3244-007; ER10-3245-006; ER10-3249-006; ER10-3250-006; ER10-2977-006; ER10-3169-009; ER10-3251-005; ER14-2382-005; ER15-621-004; ER11-2639-006; ER15-622-004; ER15-463-004; ER15-110-004; ER13-1586-006; ER10-1992-012. Applicants: Cameron Ridge, LLC, Chandler Wind Partners, LLC, Coso Geothermal Power Holdings, LLC, Foote Creek II, LLC, Foote Creek III, LLC, Foote Creek IV, LLC, Mesquite Power, LLC, Michigan Power Limited Partnership, Oak Creek Wind Power, LLC, ON Wind Energy LLC, Pacific Crest Power, LLC, Ridge Crest Wind Partners, LLC, Ridgetop Energy, LLC, San Gorgonio Westwinds II, LLC, Terra-Gen Energy Services, LLC, TGP Energy Management, LLC, Victory Garden Phase IV, LLC. Description: Notice of Non-Material Change in Status of Cameron Ridge, LLC, et al. Filed Date: 7/13/15. Accession Number: 20150713-5215. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15-1554-000.

Applicants: Midcontinent

Independent System Operator, Inc. Description: Report Filing: 2015-07-14 SA 2780 Refund Report of ATC-MP OCSA to be effective N/A.

Filed Date: 7/14/15.

Accession Number: 20150714-5030. Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-1555-000.

Applicants: Midcontinent

Independent System Operator, Inc. Description: Report Filing: 2015-07-14 SA 2781 Refund Report of ATC-SWLP OCSA to be effective N/A.

Filed Date: 7/14/15.

Accession Number: 20150714-5027. Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-2187-000. Applicants: Chief Conemaugh Power,

Description: Section 205(d) Rate Filing: Succession to Duquesne Interests to be effective 7/14/2015.

Filed Date: 7/13/15.

Accession Number: 20150713-5156. Comments Due: 5 p.m. ET 8/3/15. Docket Numbers: ER15-2188-000.

Applicants: Chief Keystone Power, LLC.

Description: Section 205(d) Rate Filing: Succession to Duquesne Interests to be effective 7/14/2015.

Filed Date: 7/13/15.

Accession Number: 20150713-5157. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15-2189-000. Applicants: Duke Energy Progress, Inc., Duke Energy Florida, Inc., Duke Energy Carolinas, LLC

Description: Section 205(d) Rate Filing: Joint OATT Amendment to be effective 9/11/2015.

Filed Date: 7/13/15.

 $Accession\ Number: 20150713-5158.$ Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15-2190-000. Applicants: Midcontinent

Independent System Operator, Inc. Description: Section 205(d) Rate Filing: 2015-07-13 Attachment J TSR Waiver Filing to be effective 9/1/2015. Filed Date: 7/13/15.

Accession Number: 20150713-5159. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15-2191-000. Applicants: Grant Wind, LLC.

Description: Baseline eTariff Filing: Application for MBR to be effective 7/ 14/2015.

Filed Date: 7/13/15.

Accession Number: 20150713-5160. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15-2192-000. Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of Service Agreement No. 3939; Queue Z2-019 to be effective 6/15/2015.

Filed Date: 7/13/15.

 $Accession\ Number: 20150713-5163.$ Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15-2193-000. Applicants: PJM Interconnection,

L.L.C., Commonwealth Edison Company.

Description: Section 205(d) Rate Filing: ComEd submits Transmission Interconnection Agreement 4212 to be effective 7/13/2015.

Filed Date: 7/13/15.

Accession Number: 20150713-5164. Comments Due: 5 p.m. ET 8/3/15.

Docket Numbers: ER15-2194-000. Applicants: SunE Solar XVII Project1, LLC.

Description: Baseline eTariff Filing: SFA to be effective 7/15/2015. Filed Date: 7/14/15.

Accession Number: 20150714-5001. Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-2195-000. Applicants: SunE Solar XVII Project2, LLC.

Description: Baseline eTariff Filing: SFA to be effective 7/15/2015. Filed Date: 7/14/15.

Accession Number: 20150714-5002. Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-2196-000. Applicants: SunE Solar XVII Project3, LLC.

Description: Baseline eTariff Filing: SFA to be effective 7/15/2015.

Filed Date: 7/14/15.

Accession Number: 20150714-5003.

Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15–2197–000.

Applicants: DTE Electric Company.

Description: Section 205(d) Rate Filing: DTE and City of Croswell Interconnection Agreement to be effective 9/1/2015.

Filed Date: 7/14/15.

Accession Number: 20150714-5024. Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-2198-000.

Applicants: DTE Electric Company.

Description: Section 205(d) Rate Filing: DTE and Village of Sebewaing Interconnection Agreement to be effective 9/1/2015.

Filed Date: 7/14/15.

Accession Number: 20150714-5025.

Comments Due: 5 p.m. ET 8/4/15.

Docket Numbers: ER15-2199-000.

Applicants: DTE Electric Company.

Description: Section 205(d) Rate Filing: DTE and Thumb Electric Cooperative Interconnection Agreement to be effective 9/1/2015.

Filed Date: 7/14/15.

Accession Number: 20150714-5026.

Comments Due: 5 p.m. ET 8/4/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: http://www.ferc.gov/ docs-filing/efiling/filing-req.pdf. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: July 14, 2015.

#### Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-17693 Filed 7-17-15; 8:45 am]

BILLING CODE 6717-01-P

#### **DEPARTMENT OF ENERGY**

#### Federal Energy Regulatory Commission

#### Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

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Docket Numbers: ER10-1836-007;
ER10-2005-007; ER11-26-007; ER10-
2551-006; ER10-1841-007; ER13-712-
007; ER10-1843-007; ER10-1844-007;
ER10-1845-007; ER10-1846-006;
ER10-1852-010; ER10-1855-006;
ER10-1897-007; ER10-1905-007;
ER10-1907-007; ER10-1918-007;
ER10-1925-007; ER10-1927-007;
ER11-2642-007; ER10-1950-007;
ER10-2006-008; ER10-1964-007;
ER10-1965-007; ER10-1970-007;
ER10-1972-007; ER10-1971-020;
ER11-4462-012; ER10-1983-007;
ER10-1984-007; ER13-2461-002;
ER10-1991-007; ER12-1660-007;
ER10-1994-006; ER10-2078-008;
ER10-1995-006.
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Applicants: Ashtabula Wind, LLC, Ashtabula Wind II, LLC, Ashtabula Wind III, LLC, Baldwin Wind, LLC, Butler Ridge Wind Energy Center, LLC, Cimarron Wind Energy, LLC, Crystal Lake Wind, LLC, Crystal Lake Wind II, LLC, Crystal Lake Wind III, LLC, Day County Wind, LLC, Florida Power & Light Company, FPL Energy Burleigh County Wind, LLC, FPL Energy Hancock County Wind, LLC, FPL Energy Mower County, LLC, FPL Energy North Dakota Wind, LLC, FPL Energy North Dakota Wind II, LLC, FPL Energy Oliver Wind I, LLC, FPL Energy Oliver Wind II, LLC, FPL Energy South Dakota Wind, LLC, Garden Wind, LLC, Hawkeye Power Partners, LLC, Lake Benton Power Partners II, LLC, Langdon Wind, LLC, NextEra Energy Duane Arnold, LLC, NextEra Energy Point Beach, LLC, NextEra Energy Power Marketing, LLC, NEPM II, LLC, Osceola Windpower, LLC, Osceola Windpower II, LLC, Pheasant Run Wind, LLC, Story Wind, LLC, Tuscola Bay Wind, LLC, Wessington Wind Energy Center, LLC White Oak Energy LLC, Wilton Wind II,

Description: Triennial Market Power Update for the Central Region of the NextEra Companies.

Filed Date: 7/10/15.

Accession Number: 20150710–5260.

Comments Due: 5 p.m. ET 9/8/15.

Docket Numbers: ER11–2489–005; ER15–1019–001; ER14–1656–004; ER14–1439–002; ER13–2308–002; ER13–2102–003; ER12–726–004; ER12–2639–003; ER12–2513–004; ER12–2512–004; ER12–2511–004;

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ER12-1435-005; ER12-1434-005;
ER12-1432-005; ER12-1431-005;
ER11-3959-004; ER11-3620-007;
ER11-2882-008; ER10-2628-002;
ER10-2449-007; ER10-2446-007;
ER10-2444-007; ER10-2442-007;
ER10-2440-007; ER10-2435-007;
ER10-2432-007.
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Applicants: Hatchet Ridge Wind, LLC, Spring Valley Wind LLC, Ocotillo Express LLC, Lyonsdale Biomass, LLC, ReEnergy Sterling CT Limited Partnership, Bayonne Plant Holding, L.L.C., Camden Plant Holding, L.L.C., Dartmouth Power Associates Limited Partnership, Elmwood Park Power, LLC, Newark Bay Cogeneration Partnership, L.P, Pedricktown Cogeneration Company LP, York Generation Company LLC, ReEnergy Ashland LLC, ReEnergy Fort Fairfield LLC, ReEnergy Livermore Falls LLC, ReEnergy Stratton LLC, ReEnergy Black River LLC, Brandon Shores LLC, C.P. Crane LLC, H.A. Wagner LLC, Raven Power Marketing LLC, Sapphire Power Marketing LLC, TrailStone Power, LLC, CSOLAR IV West, LLC, Fowler Ridge IV Wind Farm LLC, Lost Creek Wind, LLC, Post Rock Wind Power Project, LLC.

Description: Supplement to June 15, 2015 Notification of Non-Material Change in Status of the Riverstone MBR Entities.

Filed Date: 7/1/15.

Accession Number: 20150701–5369. Comments Due: 5 p.m. ET 7/22/15.

Docket Numbers: ER15–2154–000.
Applicants: Ashtabula Wind, LLC.
Description: Compliance filing:

Ashtabula Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/ 2015.

Filed Date: 7/10/15.

Accession Number: 20150710-5147. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2155–000. Applicants: Ashtabula Wind II, LLC. Description: Compliance fling:

Ashtabula Wind II, LLC Order No. 784 Compliance Filing to be effective 7/11/ 2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5148.
Comments Due: 5 p.m. ET 7/31/15.
Docket Numbers: ER15–2156–000.
Applicants: Ashtabula Wind III, LLC.
Description: Compliance filing:
Ashtabula Wind III, LLC Order No. 784

Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5149. Comments Due: 5 p.m. ET 7/31/15. Docket Numbers: ER15–2157–000.

Applicants: Baldwin Wind, LLC. Description: Compliance filing: Baldwin Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5150. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2158–000. Applicants: Butler Ridge Wind Energy Center, LLC.

Description: Compliance filing: Butler Ridge Wind Energy Center, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5151. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2159–000. Applicants: Crystal Lake Wind, LLC. Description: Compliance filing:

Crystal Lake Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/ 2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5152. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2160–000. Applicants: Crystal Lake Wind II,

LLC.

Description: Compliance filing:
Crystal Lake Wind II, LLC Order No. 784
Compliance Filing to be effective 7/11/

2015. Filed Date: 7/10/15.

Accession Number: 20150710–5153. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2161–000. Applicants: Crystal Lake Wind III, LLC

Description: Compliance filing: Crystal Lake Wind III, LLC Order No. 784 Compliance Filing to be effective 7/ 11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5154. Comments Due: 5 p.m. ET 7/31/15. Docket Numbers: ER15–2162–000. Applicants: Day County Wind, LLC.

Description: Compliance filing: Day County Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/ 2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5155. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2163–000.
Applicants: FPL Energy Burleigh

County Wind, LLC.

Description: Compliance filing: FPL

Description: Compliance filing: FPL Energy Burleigh County Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5156. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2164–000. Applicants: FPL Energy Hancock County Wind, LLC.

Description: Compliance filing: FPL Energy Hancock County Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5157. Comments Due: 5 p.m. ET 7/31/15. Docket Numbers: ER15–2165–000.

Applicants: FPL Energy Mower County, LLC.

Description: Compliance filing: FPL Energy Mower County, LLC Order No. 784 Compliance Filing to be effective 7/ 11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5158. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2166–000. Applicants: FPL Energy North Dakota Wind, LLC.

Description: Compliance filing: FPL Energy North Dakota Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5159. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2167–000. Applicants: FPL Energy North Dakota Wind II, LLC.

Description: Compliance filing: FPL Energy North Dakota Wind II, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5160. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2168–000. Applicants: FPL Energy Oliver Wind I, LLC.

Description: Compliance filing: FPL Energy Oliver Wind I, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5161. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2169–000. Applicants: FPL Energy Oliver Wind

Description: Compliance filing: FPL Energy Oliver Wind II, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710-5162. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15-2170-000.

Applicants: FPL Energy South Dakota Wind, LLC.

Description: Compliance filing: FPL Energy South Dakota Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5164. Comments Due: 5 p.m. ET 7/31/15. Docket Numbers: ER15–2171–000. Applicants: Garden Wind, LLC. Description: Compliance filing: Garden Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5165. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2172–000. Applicants: Lake Benton Power Partners II, LLC.

Description: Compliance filing: Lake Benton Power Partners II, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5166. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2173–000. Applicants: Langdon Wind, LLC.

Description: Compliance filing: Langdon Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/ 2015.

Filed Date: 7/10/15.

Accession Number: 20150710-5167. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2174–000. Applicants: NextEra Energy Duane Arnold, LLC.

Description: Compliance filing: NextEra Energy Duane Arnold, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5168. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2175–000. Applicants: NextEra Energy Point Beach, LLC.

Description: Compliance filing: NextEra Energy Point Beach, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5169. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2176–000. Applicants: Osceola Windpower, LLC.

Description: Compliance filing: Osceola Windpower, LLC Order No. 784 Compliance Filing to be effective 7/11/ 2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5170. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2177–000. Applicants: Osceola Windpower II,

Description: Compliance filing: Osceola Windpower II, LLC Order No. 784 Compliance Filing to be effective 7/ 11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5171. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2178–000. Applicants: Pheasant Run Wind, LLC. Description: Compliance filing: Pheasant Run Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/ 2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5172. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2179–000. *Applicants:* Story Wind, LLC.

*Description:* Compliance filing: Story Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5173. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2180–000. Applicants: Tuscola Bay Wind, LLC. Description: Compliance filing:

Tuscola Bay Wind, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5174. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2181–000. Applicants: Tuscola Wind II, LLC.

Description: Compliance filing: Tuscola Wind II, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

 $\begin{tabular}{ll} Accession Number: 20150710-5176. \\ Comments Due: 5 p.m. ET 7/31/15. \\ \end{tabular}$ 

Docket Numbers: ER15–2182–000. Applicants: Wessington Wind Energy Center, LLC.

Description: Compliance filing: Wessington Wind Energy Center, LLC Order No. 784 Compliance Filing to be effective 7/11/2015.

Filed Date: 7/10/15.

Accession Number: 20150710–5177. Comments Due: 5 p.m. ET 7/31/15.

Docket Numbers: ER15–2183–000. Applicants: Wilton Wind II, LLC.

Description: Compliance filing: Wilton Wind II, LLC Order No. 784 Compliance Filing to be effective 7/11/ 2015.

Filed Date: 7/10/15.

*Accession Number:* 20150710–5178. *Comments Due:* 5 p.m. ET 7/31/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing

requirements, interventions, protests, service, and qualifying facilities filings can be found at: http://www.ferc.gov/docs-filing/efiling/filing-req.pdf. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 13, 2015.

#### Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-17691 Filed 7-17-15; 8:45 am]

BILLING CODE 6717-01-P

#### **DEPARTMENT OF ENERGY**

#### Federal Energy Regulatory Commission

[Docket No. EL15-84-000]

# Caithness Long Island II, LLC v. New York Independent System Operator, Inc.; Notice of Complaint

Take notice that on July 10, 2015, pursuant to sections 206 and 306 of the Federal Power Act, 16 U.S.C. 824e and 825e and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, Caithness Long Island II, LLC (Complainant) filed a formal complaint against New York Independent System Operator, Inc. (NYISO or Respondent) alleging that NYISO's application of certain interconnection requirements to the Class Year 2015 Interconnection Facilities Study violates Commission policy and the NYISO Open Access Transmission Tariff.

The Complainant certify that copies of the complaint were served on the contacts for NYISO as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at <a href="http://www.ferc.gov">http://www.ferc.gov</a>. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the

Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at http://www.ferc.gov, using the "eLibrary" link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 10, 2015.

Dated: July 13, 2015.

#### Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-17690 Filed 7-17-15; 8:45 am]

BILLING CODE 6717-01-P

### ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2015-0021; FRL-9930-12]

#### Pesticide Product Registration; Receipt of Applications for New Active Ingredients

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

**DATES:** Comments must be received on or before August 19, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2015-0021 and the File Symbol of interest as shown in the body of this document, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <a href="http://www.epa.gov/dockets">http://www.epa.gov/dockets</a>.

#### FOR FURTHER INFORMATION CONTACT:

Jennifer Mclain, Acting Director, Antimicrobials Division (AD) (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: ADFRNotices@epa.gov.

Robert McNally, Director, Biopesticides and Pollution Prevention Division (BPPD) (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305– 7090; email address: BPPDFRNotices@ epa.gov.

Susan Lewis, Director, Registration Division (RD) (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: RDFRNotices@epa.gov.

The Division to contact is listed at the end of each application in Unit II.

#### SUPPLEMENTARY INFORMATION:

#### I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI

information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at http://www.epa.gov/dockets/comments.html.

#### II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

File Symbol: 70644–L. Docket ID number: EPA–HQ–OPP–2015–0417. Applicant: LidoChem, Inc., 20 Village Ct., Hazlet, NJ 07730. Product name: Varnimo® ST. Active ingredient: Nematocide and Plant Growth Regulator; Bacillus amyloliquefaciens strain PTA–4838 at 73.4%. Proposed classification/Use: None. Contact: BPPD.

File Symbol: 70644—A. Docket ID number: EPA—HQ—OPP—2015—0417.

Applicant: LidoChem, Inc., 20 Village Ct., Hazlet, NJ 07730. Product name: Varnimo® WSP. Active ingredient: Fungicide, Plant Growth Regulator, and Nematocide; Bacillus amyloliquefaciens strain PTA—4838 at 0.29%. Proposed classification/Use: None. Contact: BPPD.

File Symbol: 70644—T. Docket ID number: EPA—HQ—OPP—2015—0417. Applicant: LidoChem, Inc., 20 Village Ct., Hazlet, NJ 07730. Product name: Varnimo® Technical. Active ingredient: Manufacturing Use; Bacillus amyloliquefaciens strain PTA—4838 at 73.4%. Proposed classification/Use: None. Contact: BPPD.

File Symbol: 84427–R. Docket ID number: EPA–HQ–OPP–2015–0418. Applicant: University of Florida, Institute of Food and Agricultural Sciences, 700 Experiment Station Rd., Lake Alfred, FL 33850. Product name: X17–2 Papaya. Active ingredient: PlantIncorporated Protectant; Papaya Ringspot Virus Resistance Gene (Papaya Ringspot Virus Coat Protein Gene) in X17–2 Papaya at 0.00000005%. Proposed classification/Use: None. Contact: BPPD.

File Symbol: 89046–G. Docket ID number: EPA–HQ–OPP–2015–0419. Applicant: AEF Global, Inc. c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192. Product name: Bioprotec Technical. Active ingredient: Manufacturing Use; Bacillus thuringiensis subspecies kurstaki strain EVB–113–19 at 99.2%. Proposed classification/Use: None. Contact: BPPD.

File Symbol: 71512–EI and 71512–EO. Docket ID number: EPA–HQ–OPP–2015–0383. Applicant: ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio 44077. Product names: Technical Tolpyralate Herbicide and Tolpyralate 400SC Herbicide. Active ingredient: Herbicide and Tolpyralate at 97% (Technical Herbicide) and 37% (400SC Herbicide). Proposed classification/Use: Corn (field corn, sweet corn, and popcorn). Contact: RD.

File Symbol: 10163–GGG. Docket ID number: EPA–HQ–OPP–2015–0226. Applicant: Gowan Company, P.O. Box 5569, Yuma, AZ 85366. Product name: Benzobicyclon Technical. Active ingredient: Herbicide, benzobicyclon at 98%. Proposed classification/Use: Formulating into end-use products for use on rice (grain, straw). Contact: RD.

File Symbol: 10163–GGU. Docket ID number: EPA–HQ–OPP–2015–0226. Applicant: Gowan Company, P.O. Box 5569, Yuma, AZ 85366. Product name: Butte Herbicide. Active ingredients: Herbicide, benzobicyclon at 3% and halosulfuron at .64%. Proposed classification/Use: Rice (grain, straw). Contact: RD.

File Symbols: 59639-ENR, 59639-ENN, 59639–ROO, and 59639–ROI: Docket ID number: EPA-HQ-OPP-2014–0285. Applicant: Valent USA Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596. Product names: S 2200 Fungicide Technical, S 2200 3.2 FS Fungicide, S 2200 4SC VPP Fungicide, and S 2200 4SC Ag Fungicide. Active ingredient: Fungicide, S 2200 (Mandestrobin) at 88.8%, 35.1%, 43.4% and 43.4%, respectively. Proposed classification/Use: Small fruit vine climbing, except fuzzy kiwifruit crop subgroup 13-F, Low growing berry subgroup 13-07G, Rapeseed Crop Subgroup 20A, Turf, and Seed Treatment. Contact: RD.

File Symbol: 91581–R. Docket ID number: EPA–HQ–OPP–2015–0367. Applicant: I-Tech AB, Pepparedsleden 1, Gothenburg, SE43183, Sweden. Product name: Selektope. Active ingredient: Antimicrobial and Medetomidine at 99.8%. Proposed classification/Use: Antifoulant Paint Contact: AD.

File Symbol: 91581–E. Docket ID number: 2015–0367. Applicant: I-Tech AB, Pepparedsleden 1, Gothenburg, SE43183, Sweden. Product name: CMP–2 RED. Active ingredient: Antimicrobial and Medetomidine at 4.41%. Proposed classification/Use: Antifoulant Paint Contact: AD.

File Symbol: 56228–AN. Docket ID number: EPA–HQ–OPP–2015–0319. Applicant: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Policy and Program Development, Environmental and Risk Analysis Services, Unit 149, 4700 River Road, Riverdale, MD 20737. Product name: Sodium Nitrite Technical. Active ingredient: Rodenticide, Sodium Nitrite at 99%. Proposed classification/Use: Manufacturing use. Contact: RD.

Authority: 7 U.S.C. 136 et seq.

Dated: July 8, 2015.

#### Jennifer Mclain,

Acting Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 2015-17738 Filed 7-17-15; 8:45 am]

BILLING CODE 6560-50-P

#### **FEDERAL RESERVE SYSTEM**

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

**AGENCY:** Board of Governors of the Federal Reserve System.

**SUMMARY:** Notice is hereby given of the final approval of a proposed information collection by the Board of Governors of the Federal Reserve System (Board) under the Office of Management and Budget (OMB) delegated authority. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statement and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

#### FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance

Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Final approval under OMB delegated authority of the extension for three years, with revision, of the following information collection:

Report title: Report of Selected Money Market Rates.

Agency form number: FR 2420.

OMB Control number: 7100–0357.

Effective Date: October 20, 2015, for Part A-Federal Funds, Part AA-Selected Borrowings from Non-Exempt Entities, and Part B-Eurodollars. January 15, 2016, for Part C-Time Deposits and Certificates of Deposit.

Frequency: Daily.

Reporters: Domestically chartered commercial banks and thrifts that have \$18 billion or more in total assets, or \$5 billion or more in assets and meet certain unsecured borrowing activity thresholds; U.S. branches and agencies of foreign banks with total third-party assets of \$2.5 billion or more.

Estimated annual reporting hours: Commercial banks and thrifts—34,200 hours; U.S. branches and agencies of foreign banks—35,100 hours; International Banking Facilities—19,750 hours; Significant banking organizations—900 hours.

Estimated average hours per response: Commercial banks and thrifts—1.8 hours; U.S. branches and agencies of foreign banks—1.8 hours; International Banking Facilities—1.0 hour; Significant banking organizations—1.8 hours.

Number of respondents: Commercial banks and thrifts—76; U.S. branches and agencies of foreign banks—78; International Banking Facilities—79; Significant banking organizations—2.

General description of report: The FR 2420 is a mandatory report that is authorized by sections 9 and 11 of the Federal Reserve Act (12 U.S.C. 324 and 248(a)(2)), sections 7(c)(2) and 8(a) of the International Banking Act (12 U.S.C. 3105(c)(2) and 3106(a)), and section 5(c) of the Bank Holding Company Act (12 U.S.C. 1844(c)(1)(A)). Individual respondent data are regarded as confidential under the Freedom of

Information Act (FOIA) (5 U.S.C. 552(b)(4)).

Abstract: The FR 2420 is a transaction-based report that currently collects daily liability data on federal funds transactions, Eurodollar transactions, and certificates of deposit (CD) issuance from (1) domestically chartered commercial banks and thrifts that have \$26 billion or more in total assets and (2) U.S. branches and agencies of foreign banks with total third-party assets of \$900 million or more. FR 2420 data are used in the analysis of current money market conditions and will allow the Federal Reserve Bank of New York (FRBNY) to calculate and publish interest rate statistics for selected money market instruments.

Current Actions: On April 7, 2015, the Federal Reserve published a notice in the **Federal Register** (80 FR 18620) requesting public comment for 60 days on the extension, with revision, of the FR 2420. The comment period for this notice expired on June 8, 2015. The Federal Reserve received four comment letters on the proposed revisions of the FR 2420; three from trade organizations and one from a U.S. branch of a foreign bank. Substantive comments on the data collection are discussed in detail below. In addition, several technical comments were received and the Federal Reserve will update the final reporting forms and instructions for these comments, as appropriate.

#### **Summary of Public Comments**

Report Cost-Benefit

A trade organization asked if the marginal increase in information from adding new U.S. bank reporters outweighs the increase in costs and burden on these additional institutions affected by the proposal. While the Federal Reserve is sensitive to the reporting burden of the affected depository institutions, revisions to the data are being made to fulfill highpriority policy objectives. First, the expanded and enhanced data collection is expected to improve unsecured money market monitoring and augment the ability of the Federal Reserve Bank of New York, on behalf of the Federal Reserve, to analyze these markets and implement monetary policy.

Second, the data set is expected to provide robust transaction data for calculating the effective federal funds rate (EFFR), an improvement over the current rate constructed from brokered data. The collection also is expected to allow for the calculation of a new overnight bank funding rate (OBFR) that uses both federal funds and Eurodollar

data. Third, data collected under the FR 2420 report also represent an important source of information on individual depository institutions' borrowing rates, which is expected to allow for more effective monitoring of firm-specific liquidity risks for purposes of supervisory surveillance.

Given these critical uses for the data, the Federal Reserve is seeking to ensure that the reporting panel captures entities that are meaningfully involved in unsecured money markets and that it remains robust to changes in borrower composition in these markets. Additional U.S. bank reporters are necessary to provide insight into a distinct and important segment of the federal funds market. The federal funds borrowing in this segment can represent a significant proportion of overall activity in certain market environments, and can occur at rates that are distinct from funding activity conducted by other institutions. However, the Federal Reserve understands the need to strike a balance between reporting burden and the collection of information required to fulfill its policy objectives. As such, adjustments are being made to the assetsize thresholds to reduce reporting burden, as discussed below. In addition, exceptions may be made for those institutions that meet the asset-size threshold but can demonstrate that they have an ongoing business model that results in a negligible amount of activity in these markets. The "Reporting Exception" section below provides more information on how an exception may be obtained.

Asset Size and Activity Thresholds

A trade organization wrote that the asset-size threshold imposes costs on institutions that may not have substantial activity and noted that, according to Call Report data, institutions with between \$15 billion and \$26 billion in assets hold only about five percent of total federal funds purchased. This trade organization noted that the activity threshold approach is more targeted and should be used for any institution to which the Federal Reserve intends to extend reporting requirements.

Asset-size thresholds create a stable panel of reporters, by ensuring that banks of meaningful size will be consistently required to report activity in a timely manner. This stable panel of banks is necessary to effectively analyze trends in unsecured funding markets and publish the EFFR and OBFR. The Federal Reserve proposed a lower asset-size threshold in order to create a more comprehensive dataset that captures an important segment of the federal funds

market that is not currently covered in the existing criteria. Collectively, the federal funds activity of domestic depository institutions with assets between \$15 billion and \$26 billion can be notable. Call Report data suggest that the aggregate amount of federal funds activity of banks in this asset size varies and has, at times, represented more than 10 percent of federal funds activity. In addition, in the current market environment, borrowing by these institutions often occurs at different rates than seen in the current sample and represents an important segment of the market that the current FR 2420 report does not capture.

Activity thresholds, on the other hand, are beneficial for providing insight into activity that is outside the scope of the regular panel of reporters, and represents an important supplement to the asset-size thresholds. However, activity thresholds used alone can create gaps in reporting and a more inconsistent panel of banks. These thresholds necessarily require a lookback period to measure activity and some forward period to prepare for reporting; thus, there is a significant lag between the threshold for activity being met and the commencement of reporting. The Federal Reserve considered relying more heavily on an activity threshold and found that the panel of banks was more inconsistent and the data capture was less complete.

Nonetheless, the Federal Reserve understands the need to find a balance between the burden being placed on reporting institutions and the achievement of reporting objectives. In light of the burden on smaller institutions of FR 2420 reporting, the Federal Reserve will retain the asset-size thresholds, but raise the minimum reporting threshold for domestically chartered commercial banks and thrifts from \$15 billion to \$18 billion. With this revised criteria, U.S. institutions with between \$15 billion and \$18 billion in assets will now only report if they meet the activity threshold. This change in threshold will result in a reduction in the number of additional, smaller institutions being required to report under the asset-size threshold.

#### Reporting Exception

A trade organization asked for clarification on how and with what frequency institutions with ongoing business models that result in negligible activity can apply for exceptions to filing the FR 2420 report. Institutions can request a review of their reporting requirement at any point that they believe the reporting is an unreasonable burden. Requests should be made in

writing and provide a look back of the data for at least two quarters and provide justification on why continuing to provide these data causes an undue burden.

#### Implementation Date

Two trade organizations requested additional time to implement the revisions. One organization noted that the proposed timeline would be difficult to implement, as the recommended revisions add and redefine several elements of the FR 2420 report. This organization stated that the current panel of banks would need two quarters after final requirements and newly covered institutions would need one vear. A second organization stated that although the proposal was welldeveloped and vetted, it would be difficult to commit systems and personnel until the final Federal Register notice. This organization asked the Federal Reserve to re-assess the proposed date, with not less than 6 months from the final requirements for implementation.

The revisions to the FR 2420 data are being implemented to meet high priority policy objectives. Most of the reporters under the new criteria are active reporters under the existing criteria. However, in order to provide the lead time for new reporters to prepare for reporting and still fulfill these objectives, the initially proposed reporting date of September 9, 2015 will be extended to October 20, 2015 for Part A-Federal Funds, Part AA-Selected Borrowings from Non-Exempt Entities, and Part B-Eurodollars. The reporting date for Part C-Time Deposits and Certificates of Deposit will be extended until January 15, 2016. This delay will allow reporters to focus on the changes applicable to the most time-sensitive parts of the report.

#### Submission Deadline

A trade organization noted the 7 a.m. deadline imposes administrative costs for covered institutions and these costs are magnified, on a relative basis, for smaller institutions, which have fewer resources. A second organization stated that banks continue to experience challenges in meeting the 7 a.m. deadline for federal funds reporting as it conflicts with normal batch processing. This organization noted the time will also be a challenge for the expanded Eurodollar reporting requirements.

After considering these comments, the Federal Reserve determined that federal funds and Eurodollar data are needed by 7 a.m. each business day for the preceding day's reportable transactions

to support the implementation of monetary policy and daily market monitoring. Therefore, the Federal Reserve is retaining the 7 a.m. deadline in the final report. The FR 2420 data provide a key insight on the previous day's unsecured market activity in the morning when the Federal Reserve is monitoring markets for the purposes of implementing monetary policy. In addition, in 2016, the data will be used as the source for daily calculation of the EFFR and OBFR. The EFFR is published in the morning in order to provide the market with a timely view on the previous day's activity.

#### Supervisory Purpose

A trade organization objected to the broadening of the purpose of the reporting form to include a supervisory component. According to this organization, the timing and frequency of FR 2420 reporting makes it difficult for covered institutions to subject data to proper regulatory reporting controls. The trade organization would prefer the Federal Reserve to use the supervisory and reporting framework already in place to monitor individual firm liquidity conditions. The organization requested clarification on the interaction of the FR 2420 with the FR 2052b, which eliminated the requirement for daily reporting from institutions with between \$15 to \$26 billion in total assets after acknowledging through the FR 2052bimplementation process that daily reporting is burdensome and unnecessary for these institutions. The organization also wrote that given significant changes being implemented to the FR 2052a, banks do not have enough information to comment on whether the FR 2420 report is duplicative or complementary. The organization noted that not all institutions that would be required to file the FR 2420 are required to file the FR 2052b. Furthermore, according to this organization, the FR 2420 collection encompasses institutions for whom the Federal Reserve is not the primary regulator, and it is unclear by which process the Federal Reserve will coordinate with the other banking

FR 2420 data are used by the Federal Reserve to carry out both monetary policy and supervisory functions. Although daily reporting for smaller institutions may not be required for supervisory surveillance on the FR 2052b, reporting at a daily frequency is required on the FR 2420 for analysis of current money market conditions and publication of the EFFR and OBFR. Institutions with asset sizes under the

\$26 billion represent an important segment of the federal funds market that is not currently captured by the FR 2420 report, and collecting their borrowing transactions is necessary for understanding unsecured money markets. As noted above, the minimum asset-size threshold for reporting by U.S. institutions on the FR 2420 is being raised to \$18 billion in order to balance the need to capture this information with the reporting burden on smaller institutions. This higher minimum threshold will eliminate the need for daily reporting for many smaller institutions. Furthermore, including a supervisory component to the FR 2420 report is not expected to increase, in itself, the burden on institutions required to file an FR 2420 since all report submissions are subject to control, audit, and governance protocols.

Utilization of the FR 2420 report for supervisory purposes will complement existing liquidity monitoring reports and allow the Federal Reserve to reduce reporting requirements in those reports. Specifically, with regard to the interaction between the FR 2420 and FR 2052, the Federal Reserve has reviewed the current and proposed reports and confirms there is no duplicated information or material overlaps between these reports. A subset of the FR 2420 pricing data was already being collected on the FR 2052a as part of supervisory liquidity monitoring. Going forward, information contained on the FR 2420 will replace certain information currently gathered on the FR 2052a, as these data elements will be dropped from the FR 2052a collection. Pricing information on the FR 2052b will not change, as that data is not similar to FR 2420 data. However, the amended FR 2420 will offer greater insight on the borrowing costs for these firms' liabilities. Pricing information, when used in tandem with liquidity data, is an area that supervisors review when gauging a firm's overall liquidity profile. Rapid changes in pricing can indicate a firm is entering a period of constrained market access and subsequent liquidity stress.

For institutions whose primary regulator is not the Federal Reserve and who do not file FR 2052 reports, the FR 2420 data is intended primarily for monetary policy purposes. The Federal Reserve does not plan to share these data with other agencies.

#### Clarifications and Other Issues

One trade organization asked for clarification on several definitions, including counterparty types, embedded options on CDS, borrowings from GSEs

and FHLBs, deposits from non-financial corporations, and the office identifier on Part B. Each of these definitions will be updated with further clarification in the reporting instructions. The organization also asked for a formal process for Frequently Asked Questions. The Federal Reserve will have a process to document reporting questions and communicate these to reporters. Lastly, the organization asked for the Reporting Central application to be open for testing as soon as possible. The application will be available for testing at least one month before the implementation dates.

One commenter provided additional comments outside the scope of the data collection proposal that focused on the calculation of the published rates.

Board of Governors of the Federal Reserve System, July 15, 2015.

#### Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015-17713 Filed 7-17-15; 8:45 am]

BILLING CODE 6210-01-P

### FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

#### Sunshine Act; Notice of Meeting

TIME AND DATE: 9:00~a.m. (Eastern Time) July 27, 2015.

**PLACE:** 10th Floor Board Meeting Room, 77 K Street NE., Washington, DC 20002. **STATUS:** Parts will be open to the public and parts closed to the public.

#### MATTERS TO BE CONSIDERED:

Open to the Public

- 1. Approval of the Minutes of the June 25, 2015 Board Member Meeting
- 2. Monthly Reports
  - (a) Monthly Participant Activity Report
  - (b) Legislative Report
- 3. Quarterly Reports
  - (a) Investment Policy Report
  - (b) Vendor Financials
  - (c) Audit Status
  - (d) Budget Review
  - (e) Project Activity Report
- 4. Withdrawal Options
- 5. Mutual Fund Window Project and Policy
- 6. Investment Consultant Memo
- 7. Impact of Proposed Changes to G Fund
- 8. Investment Advice Discussion

Closed to the Public

- 9. Litigation
- 10. Security
- 11. Personnel

#### CONTACT PERSON FOR MORE INFORMATION:

Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

Dated: July 16, 2015.

#### James Petrick,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2015–17870 Filed 7–16–15; 4:15 pm]

BILLING CODE 6760-01-P

#### FEDERAL TRADE COMMISSION

#### Agency Information Collection Activities; Proposed Collection; Comment Request

**AGENCY:** Federal Trade Commission ("FTC" or "Commission").

**ACTION:** Notice.

SUMMARY: The FTC intends to ask the Office of Management and Budget ("OMB") to extend through November 30, 2018, the current Paperwork Reduction Act ("PRA") clearance for the information collection requirements in the FTC Red Flags, Card Issuers, and Address Discrepancies Rules <sup>1</sup> ("Rules"). That clearance expires on November 30, 2015.

**DATES:** Comments must be submitted by September 18, 2015.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Red Flags Rule, PRA Comment, Project No. P095406" on your comment, and file your comment online at https://ftcpublic.commentworks.com/ ftc/RedFlagsPRA by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

#### FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be addressed to Steven Toporoff, Attorney, Bureau of Consumer Protection, (202) 326–2252, Federal Trade Commission, 600 Pennsylvania Avenue, Washington, DC 20580.

#### SUPPLEMENTARY INFORMATION:

#### I. Overview of the Rules

The Red Flags Rule requires financial institutions and certain creditors to develop and implement written Identity

<sup>&</sup>lt;sup>1</sup> 16 CFR 681.1; 16 CFR 681.2; 16 CFR part 641.

Theft Prevention Programs ("Program"). The Card Issuers Rule requires credit and debit card issuers ("card issuers") to assess the validity of notifications of address changes under certain circumstances. The Address Discrepancy Rule provides guidance on what users of consumer reports must do when they receive a notice of address discrepancy from a nationwide consumer reporting agency ("CRA"). Collectively, these three anti-identity theft provisions are intended to prevent impostures from misusing another person's personal information for a fraudulent purpose.

The Rules implement sections 114 and 315 of the Fair Credit Reporting Act ("FCRA"), 15 U.S.C. 1681 et seq., to require businesses to undertake measures to prevent identity theft and increase the accuracy of consumer

reports.

Since promulgation of the original Rule, President Obama signed the Red Flag Program Clarification Act of 2010 ("Clarification Act"), which narrowed the definition of "creditor" for purposes of the Red Flags Rule. Specifically, the Clarification Act limits application of the Red Flags Rule to creditors that regularly and in the ordinary course of business: (1) Obtain or use consumer reports, directly or indirectly, in connection with a credit transaction; (2) furnish information to consumer reporting agencies in connection with a credit transaction; or (3) advance funds to or on behalf of a person, based on a person's obligation to repay the funds to or on behalf of a person, based on a person's obligation to repay the funds or on repayment from specific property pledged by or on the person's behalf. This third prong does not include a creditor that advances funds on behalf of a person for expenses incidental to a service provided by the creditor to that person.

# II. Description of Collection of Information

#### A. FCRA Section 114

The Red Flags Rule requires financial institutions and covered creditors to develop and implement a written Program to detect, prevent, and mitigate identity theft in connection with existing accounts or the opening of new accounts. Under the Rule, financial institutions and certain creditors must conduct a periodic risk assessment to determine if they maintain "covered accounts." The Rule defines the term "covered account" as either: (1) A consumer account that is designed to permit multiple payments or transactions, or (2) any other account for

which there is a reasonably foreseeable risk of identity theft. Each financial institution and covered creditor that has covered accounts must create a written Program that contains reasonable policies and procedures to identify relevant indicators of the possible existence of identity theft ("red flags"); detect red flags that have been incorporated into the Program; respond appropriately to any red flags that are detected to prevent and mitigate identity theft; and update the Program periodically to ensure it reflects change in risks to customers.

The Red Flags Rule also requires financial institutions and covered creditors to: (1) Obtain approval of the initial written Program by the board of directors; a committee thereof or, if there is no board, an appropriate senior employee; (2) ensure oversight of the development, implementation, and administration of the Program; and (4) exercise appropriate and effective oversight of service provider arrangements.

In addition, the Rules implement the section 114 requirement that card issuers generally must assess the validity of change of address notifications. Specifically, if the card issuer receives a notice of change of address for an existing account and, within a short period of time (during at least the first 30 days), receives a request for an additional or replacement card for the same account, the issuer must follow reasonable policies and procedures to assess the validity of the change of address.

#### B. FCRA Section 315

In implementing section 315 of the FCRA, the Rules require each user of consumer reports to have reasonable policies and procedures in place to employ when the user receives a notice of address discrepancy from a CRA. Specifically, each user of consumer reports must develop reasonable policies and procedures to: (1) Enable the user to form a reasonable belief that a consumer report relates to the consumer about whom it has requested the report, when the user receives a notice of address discrepancy; and (2) furnish an address for the consumer that the user has reasonably confirmed is accurate to the CRA from which it receives a notice of address discrepancy, if certain conditions are met.

#### III. Burden Estimates

Under the PRA, 44 U.S.C. 3501–3521, Federal agencies must get OMB approval for each collection of information they conduct or sponsor. "Collection of information" includes

agency requests or requirements to submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). The figures below reflect FTC staff's estimates of the hours burden and labor costs to complete the tasks described above that fall within reporting, disclosure, or recordkeeping requirements. FTC staff believes that the Rules impose negligible capital or other non-labor costs, as the affected entities are likely to have the necessary supplies and/or equipment already (e.g., offices and computers) for the information collection described herein.

Overall estimated burden hours regarding sections 114 and 315, combined, total 2,296,863 hours and the associated estimated labor costs are \$92,465,982. Staff assumes that affected entities will already have in place, independent of the Rule, equipment and supplies necessary to carry out the tasks necessary to comply with it.

#### A. FCRA Section 114

#### 1. Estimated Hours Burden—Red Flags Rule

As noted above, the Rule requires financial institutions and certain creditors with covered accounts to develop and implement a written Program. Under the FCRA, financial institutions over which the FTC has jurisdiction include state chartered credit unions and certain insurance companies.

Although narrowed by the Clarification Act, the definition of "creditor" still covers a broad array of entities. Moreover, the Clarification Act does not set forth any exemptions from Rule coverage. Rather, application of the Rule depends upon an entity's course of conduct, not its status as a particular type of business. For these reasons, it is difficult to determine precisely the number of creditors subject to the FTC's jurisdiction. There are numerous small businesses under the FTC's jurisdiction that may qualify as "creditors," and there is no formal way to track them. Nonetheless, FTC staff estimates that the Rule's requirement to have a written Program affects 6,298 financial institutions<sup>2</sup> and 162,295 creditors.<sup>3</sup>

Continued

<sup>&</sup>lt;sup>2</sup> The total number of financial institutions is derived from an analysis of state credit unions and insurers within the FTC's jurisdiction using 2012 Census data ("County Business Patterns," U.S.) and other online industry data.

<sup>&</sup>lt;sup>3</sup> The total number of creditors (162,295) is derived from an analysis of 2012 Census data and industry data for businesses or organizations that market goods and services to consumers or other businesses or organizations subject to the FTC's jurisdiction, reduced by entities not likely to: (1)

To estimate burden hours for the Red Flags Rule under section 114, FTC staff divided affected entities into two categories, based on the nature of their business: (1) Entities that are subject to high risk of identity theft and (2) entities that are subject to a low risk of identity theft, but have covered accounts that will require them to have a written Program.

#### a. High-Risk Entities

FTC staff estimates that high-risk entities 4 will each require 25 hours to create and implement a written Program, with an annual recurring burden of one hour. FTC staff anticipates that these entities will incorporate into their Program policies and procedures that they likely already have in place. Further, FTC staff estimates that preparation for an annual report will require each high-risk entity four hours initially, with an annual recurring burden of one hour. Finally, FTC staff believes that many of the highrisk entities, as part of their usual and customary business practice, already take steps to minimize losses due to fraud, including conducting employee training. Accordingly, only relevant staff need be trained to implement the Program: For example, staff already trained as part of a covered entity's antifraud prevention efforts do not need to be re-trained as incrementally needed. FTC staff estimates that training connected with the implementation of a Program of a high-risk entity will require four hours, and annual training thereafter will require one hour.

Thus, estimated hours for high-risk entities are as follows:

• 101,328 high-risk entities subject to the FTC's jurisdiction at an average annual burden of 13 hours per entity [average annual burden over 3-year clearance period for creation and implementation of a Program ((25+1+1)/ 3), plus average annual burden over 3year clearance period for staff training ((4+1+1)/3), plus average annual burden over 3-year clearance period for preparing an annual report ((4+1+1)/3)], for a total of 1,317,264 hours.

#### b. Low-Risk Entities

Entities that have a minimal risk of identity theft,5 but that have covered

accounts, must develop a Program; however, they likely will only need a streamlined Program. FTC staff estimates that such entities will require one hour to create such a Program, with an annual recurring burden of five minutes. Training staff of low-risk entities to be attentive to future risks of identity theft should require no more than 10 minutes in an initial year, with an annual recurring burden of five minutes. FTC staff further estimates that these entities will require, initially, 10 minutes to prepare an annual report, with an annual recurring burden of five

Thus, the estimated hours burden for low-risk entities is as follows:

 60,974 low risk entities that have covered account subject to the FTC's jurisdiction at an average annual burden of approximately 37 minutes per entity [average annual burden over 3-year clearance period for creation and implementation of streamlined Program ((60+5+5)/3), plus average annual burden over 3-year clearance period for staff training ((10+5+5)/3), plus average annual burden over 3-year clearance period for preparing annual report ((10+5+5)/3), for a total of 37,600 hours.

#### 2. Estimated Hours Burden—Card Issuers Rule

As noted above, section 114 also requires financial institutions and covered creditors that issue credit or debit cards to establish policies and procedures to assess the validity of a change of address request, including notifying the cardholder or using another means of assessing the validity of the change of address.

 FTC staff estimates that the Rule affects as many as 16,3016 card issues within the FTC's jurisdiction. FTC staff believes that most of these card issuers already have automated the process of notifying the cardholder or are using another means to assess the validity of the change of address, such that implementation will pose no further burden. Nevertheless, taking a conservative approach, FTC staff estimates that it will take each card issuer 4 hours to develop and implement policy and procedures to assess the validity of a change of address request for a total burden of 65,204 hours.

Thus, the total average annual estimated burden for Section 114 is 1,420,068 hours.

#### 3. Estimated Cost Burden—Red Flags and Card Issuers Rules

The FTC staff estimates labor costs by applying appropriate estimated hourly cost figures to the burden hours described above. It is difficult to calculate with precision the labor costs associated with compliance with the Rule, as they entail varying compensation levels of management (e.g., administrative services, computer and information systems, training and development) and/or technical staff (e.g., computer support specialists, systems analysts, network and computer systems administrators) among companies of different sizes. FTC staff assumes that for all entities, professional technical personnel and/or management personnel will create and implement the Program, prepare the annual report, and train employees, at an hourly rate of \$54.7

Based on the above estimates and assumptions, the total annual labor costs for all categories of covered entities under the Red Flags and Card Issuers Rules for Section 114 is \$76,683,672 (1,420,068 hours x \$54).

#### B. FCRA Section 315—The Address Discrepancy Rule

As discussed above, the Rule's implementation of Section 315 provides guidance on reasonable policies and procedures that a user of consumer reports must employ when a user receives a notice of address discrepancy from a CRA. Given the broad scope of users of consumer reports, it is difficult to determine with precision the number of users of consumer reports that are subject to the FTC's jurisdiction. As noted above, there are numerous small businesses under the FTC's jurisdiction, and there is no formal way to track them; moreover, as a whole, the entities under the FTC's jurisdiction are so varied that there are no general sources that provide a record of their existence. Nonetheless, FTC staff estimates that the Rule's implementation of section 315 affects approximately 1,875,275 users of

Obtain credit reports, report credit transactions, or advance loans; and (2) entities not likely to have covered accounts under the Rule.

<sup>&</sup>lt;sup>4</sup> High-risk entities include, for example, financial institutions within the FTC's jurisdiction and utilities, motor vehicle dealerships, telecommunications firms, colleges and universities, and hospitals.

<sup>&</sup>lt;sup>5</sup> Low-risk entities include, for example, public warehouse and storage firms, nursing and residential care facilities, automotive equipment

rental and leasing firms, office supplies and stationery stores, fuel dealers, and financial transactions processing firms.

<sup>&</sup>lt;sup>6</sup> Card issuers within the FTC's jurisdiction include, for example, state credit unions, general retail merchandise stores, colleges and universities,

<sup>&</sup>lt;sup>7</sup> This estimate is based on mean hourly wages found at http://www.bls.gov/news.release/ ocwage.t01.htm ("Occupational Employment and Wages—May 2014," U.S. Department of Labor, released March 2015, Table 1 ("National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2014") for the various managerial and technical staff support exemplified above (administrative service managers, computer & information systems managers, training & development managers, computer systems analysts, network & computer systems analysts, computer support specialists).

consumer reports subject to the FTC's jurisdiction.<sup>8</sup> Commission staff estimates that approximately 10,000 of these users will receive notice of a discrepancy, in the course of their usual and customary business practices, and thereby have to furnish to CRAs an address confirmation.<sup>9</sup>

For section 315, as detailed below, FTC staff estimates that the average annual burden during the three-year period for which OMB clearance is sought will be 876,795 hours with an associated labor cost of \$15,782,310.

#### 1. Estimated Hours Burden

Prior to enactment of the Address Discrepancy Rule, users of consumer reports could compare the address on a consumer report to the address provided by the consumer and discern for themselves any discrepancy. As a result, FTC staff believes that many users of consumer reports have developed methods of reconciling address discrepancies, and the following estimates represent the incremental amount of time users of consumer reports may require to develop and comply with the policies and procedures for when they receive a notice of address discrepancy.

#### a. Customer Verification

Given the varied nature of the entities under the FTC's jurisdiction, it is difficult to determine precisely the appropriate burden estimates. Nonetheless, FTC staff estimates that it would require an infrequent user of consumer reports no more than 16 minutes to develop and comply with the policies and procedures that it will employ when it receives a notice of address discrepancy, while a frequent user might require one hour. Similarly, FTC staff estimates that, during the remaining two years of clearance, it may take an infrequent user no more than one minute to comply with the policies and procedures it will employ when it receives a notice of address discrepancy, while a frequent user might require 45 minutes. Taking into account these extremes, FTC staff estimates that, during the first year, it will take users of consumer reports under the FTC's jurisdiction an average of 38 minutes

[the midrange between 16 minutes and 60 minutes] to develop and comply with the policies and procedures that they will employ when they receive a notice of address discrepancy. FTC staff also estimates that the average recurring burden for users of consumer reports to comply with the Rule will be 23 minutes [the midrange between one minute and 45 minutes].

Thus, for these 1,875,275 entities, the average annual burden for each of them to perform these collective tasks will be 28 minutes  $[(38 + 23 + 23) \div 3]$ ; cumulatively, 875,128 hours.

#### b. Address Verification

For the estimated 10,000 users of consumer reports that will additionally have to furnish to CRAs an address confirmation upon notice of a discrepancy, staff estimates that these entities will require, initially, 30 minutes to develop related policies and procedures. But, these 10,000 affected entities likely will have automated the process of furnishing the correct address in the first year of a three-year PRA clearance cycle. Thus, allowing for 30 minutes in the first year, with no annual recurring burden in the second and third years of clearance, yields an average annual burden of 10 minutes per entity to furnish a correct address to a CRA, for a total of 1,667 hours.

#### 2. Estimated Cost Burden

FTC staff assumes that the policies and procedures for compliance with the address discrepancy part of the Rule will be set up by administrative support personnel at an hourly rate of \$18.10 Based on the above estimates and assumptions, the total annual labor cost for the two categories of burden under section 315 is \$15,782,310.

## C. Burden Totals for FCRA Sections 114 and 315

Cumulatively, then, estimated burden is 2,296,863 hours (1,420,068 hours for section 114 and 876,795 hours for section 315) and \$92,465,982 (\$76,683,672 and \$15,782,310) in associated labor costs.

#### IV. Request for Comment

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before [60 days after publication]. Write: "Red Flags Rule, PRA Comment, Project No. P095406" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at <a href="http://ftc.gov/os/publiccomments.shtm">http://ftc.gov/os/publiccomments.shtm</a>. As a matter of discretion, the Commission tries to remove individual's home contact information from comments before placing them on the Commission Web site

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number, or other state identification number of foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information . . . which is privileged or confidential]" as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, don't include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). 11 Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <a href="https://ftcpublic.commentworks.com/ftc/RedFlagsPRA">https://ftcpublic.commentworks.com/ftc/RedFlagsPRA</a>, by following the instructions on the web-based form. When this Notice appears at <a href="http://www.regulations.gov/#!home">http://www.regulations.gov/#!home</a>, you also

<sup>&</sup>lt;sup>8</sup> This estimate is derived from an analysis of Census databases of U.S. businesses based on NAICS codes for businesses in industries that typically use consumer reports from CRAs described in the Rule, which total 1,875,275 users of consumer reports subject to the FTC's jurisdiction.

<sup>&</sup>lt;sup>9</sup>Report to Congress Under Sections 318 and 319 of the Fair and Accurate Credit Transactions of 2003, Federal Trade Commission, 80 (Dec. 2004) available at http://www.ftc.gov/reports/facta/041209factarpt.pdf.

<sup>&</sup>lt;sup>10</sup> This estimate—rounded to the nearest dollar—is based on mean hourly wages for all management occupations found within the "Bureau of Labor Statistics, Economic News Release," March 25, 2015, Table 1, "National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2014." http://www.bls.gov/news.release/ocwage.to1.htm.

<sup>&</sup>lt;sup>11</sup>In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR 4.9(c).

may file a comment through that Web site.

If you file your comment on paper, write "Red Flags Rule PRA, Project No. P095406" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite CC–5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before September 18, 2015. For information on the Commission's privacy policy, including routine uses by the Privacy Act, see <a href="http://www.ftc.gov/ftc/privacy.htm">http://www.ftc.gov/ftc/privacy.htm</a>.

#### David C. Shonka,

Principal Deputy General Counsel.
[FR Doc. 2015–17764 Filed 7–17–15; 8:45 am]

#### FEDERAL TRADE COMMISSION

[File No. 141 0207]

Dollar Tree, Inc. and Family Dollar Stores, Inc.; Analysis of Proposed Consent Orders To Aid Public Comment

**AGENCY:** Federal Trade Commission. **ACTION:** Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before August 3, 2015.

ADDRESSES: Interested parties may file a

comment at https:// ftcpublic.commentworks.com/ftc/ dollartreeconsent online or on paper, by following the instructions in the

Request for Comment part of the SUPPLEMENTARY INFORMATION section below. Write "Dollar Tree, Inc. and Family Dollar Stores, Inc.—Consent Agreement; File No. 141–0207" on your comment and file your comment online at https://ftcpublic.commentworks.com/ftc/dollartreeconsent by following the instructions on the web-based form. If

you prefer to file your comment on paper, write "Dollar Tree, Inc. and Family Dollar Stores, Inc.—Consent Agreement; File No. 141–0207" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Sean Pugh, Bureau of Competition, (202–326–3201), 600 Pennsylvania Avenue NW., Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for July 2, 2015), on the World Wide Web, at http://www.ftc.gov/ os/actions.shtm.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 3, 2015. Write "Dollar Tree, Inc. and Family Dollar Stores, Inc.—Consent Agreement; File No. 141-0207" on your comment. Your comment-including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at http:// www.ftc.gov/os/publiccomments.shtm. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible

for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR § 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR § 4.9(c).¹ Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at https://ftcpublic.commentworks.com/ftc/dollartreeconsent by following the instructions on the web-based form. If this Notice appears at http://www.regulations.gov/#!home, you also may file a comment through that Web site.

If you file your comment on paper, write "Dollar Tree, Inc. and Family Dollar Stores, Inc.—Consent Agreement; File No. 141-0207" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service

Visit the Commission Web site at http://www.ftc.gov to read this Notice and the news release describing it. The FTC Act and other laws that the

<sup>&</sup>lt;sup>1</sup> In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR § 4.9(c).

Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before August 3, 2015. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <a href="http://www.ftc.gov/ftc/privacy.htm">http://www.ftc.gov/ftc/privacy.htm</a>.

#### Analysis of Agreement Containing Consent Orders To Aid Public Comment

#### I. Introduction and Background

The Federal Trade Commission ("Commission") has accepted for public comment, subject to final approval, an Agreement Containing Consent Orders ("Consent Order") from Dollar Tree, Inc. ("Dollar Tree") and Family Dollar Stores, Inc. ("Family Dollar"), (collectively, the "Respondents"). On July 27, 2014, Dollar Tree and Family Dollar entered into an agreement whereby Dollar Tree would acquire Family Dollar for approximately \$9.2 billion (the "Acquisition"). The purpose of the proposed Consent Order is to remedy the anticompetitive effects that otherwise would result from Dollar Tree's acquisition of Family Dollar. Under the terms of the proposed Consent Order, Respondents are required to divest 330 stores in local geographic markets (collectively, the "relevant markets") in 35 states to the Commission-approved buyer. The divestitures must be completed within 150 days from the date of the Acquisition. The Commission and Respondents have agreed to an Order to Maintain Assets to maintain the viability of Respondents' assets until they are transferred to the Commissionapproved buyer.

The proposed Consent Order has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission again will review the proposed Consent Order and any comments received, and decide whether the Consent Order should be withdrawn, modified, or made final.

The Commission's Complaint alleges that the Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by removing an actual, direct, and substantial competitor in localized geographic markets in 222 cities

nationwide.<sup>2</sup> The elimination of this competition would result in significant competitive harm; specifically the Acquisition will allow the combined entity to increase prices unilaterally above competitive levels. Similarly, absent a remedy, there is significant risk that the merged firm may decrease the quality and service aspects of its stores. The proposed Consent Order would remedy the alleged violations by requiring divestitures to replace competition that otherwise would be lost in these markets because of the Acquisition.

#### II. The Respondents

As of January 31, 2015, Dollar Tree operated 5,157 discount general merchandise retail stores across the United States under the Dollar Tree and Deals banners. Presently, Dollar Tree banner stores are located in 48 states and the District of Columbia, while Deals banner stores are currently located in 18 states and the District of Columbia. In the Dollar Tree banner stores, Dollar Tree sells a wide selection of everyday basic, seasonal, closeout, and promotional merchandise for \$1 or less. At its Deals banner stores, Dollar Tree offers an expanded assortment of this merchandise at prices generally less than \$10. Dollar Tree and Deals banner stores range in size from 8,000 to 12,000 square feet of selling space and typically carry between 6,600 to 7,000 stock keeping units ("SKUs").

As of February 28, 2015, Family Dollar operated approximately 8,184 discount general merchandise retail stores nationwide. Family Dollar sells an assortment of consumables, home products, apparel and accessories, seasonal items, and electronic merchandise at prices generally less than \$10. Currently, Family Dollar stores are located in 46 states and the District of Columbia. Stores typically have 7,150 square feet of selling space and carry approximately 6,500 to 7,000 SKUs.

## III. Competition in the Relevant Markets

Dollar stores are small-format, deepdiscount retailers that sell an assortment of consumables and non-consumables, including food, home products, apparel and accessories, and seasonal items, at prices typically under \$10. Dollar stores differentiate themselves from other retailers on the basis of both convenience and value by offering a broad assortment but limited variety of general merchandise items at discounted prices in stores with small footprints (*i.e.*, approximately 7,000 to 10,000 square feet of selling space), located relatively close to consumers' homes or places of work.<sup>3</sup> Customers often shop at dollar stores as part of a "fill-in" shopping trip. Dollar stores typically compete most closely with other dollar stores that provide the same kind of convenient shopping trip for discounted general merchandise.

Walmart competes closely with dollar stores and offers a wide assortment of products at deeply-discounted prices. Although Walmart does not provide the same kind of convenience as that of dollar stores given its less-accessible locations, larger store footprints, and greater assortment of products, Walmart nevertheless competes closely with dollar stores by offering a comparable or better value to consumers in terms of pricing. For purposes of this matter, "discount general merchandise retail stores" refers to dollar stores and the retailer Walmart.

Although other retail stores (i.e., supermarkets, pharmacies, mass merchandisers, and discount specialty merchandise retail stores) often sell discounted merchandise similar to that offered by dollar stores and Walmart, these other retailers generally are not as effective at constraining Respondents as are other discount general merchandise retail stores.<sup>4</sup> These other retailers do not offer the same value as Walmart or the same combination of convenience and value offered by dollar stores, which tends to make them less effective substitutes for discount general merchandise retail stores. As a result, consumers shopping at discount general merchandise retail stores are unlikely to significantly increase purchases of discounted merchandise at other retailers in response to a small but significant price increase at discount general merchandise retail stores. However, in certain geographic markets, typically characterized by high population density, where the number and geographic proximity of these other retailers is substantial relative to the

<sup>&</sup>lt;sup>2</sup> The list of cities in which stores will be divested is attached as Appendix A. The list of stores to be divested is attached to the Decision and Order as Schedule A.

<sup>&</sup>lt;sup>3</sup> The term "dollar stores" as used here includes stores operated by Respondents, Dollar General, 99 Cents Only, and Fred's Super Dollar. Independently-owned retailers that sell discounted merchandise at the \$1 or multi-price point in substantially smaller stores are not included.

<sup>&</sup>lt;sup>4</sup>The term "supermarkets" as used here includes traditional supermarkets such as Kroger and Publix, as well as supermarkets included within hypermarkets such as SuperTarget or Kroger's Fred Meyer banner. The term "pharmacies" includes national retail drug stores such as CVS, Rite Aid, and Walgreens. The term "mass merchandisers" includes retailers such as Target and K-Mart. The term "discount specialty merchandise retail stores" includes retailers such as Big Lots and Aldi.

competing discount general merchandise retail stores, the collective presence of these other retailers acts as a more significant price constraint on the discount general merchandise retail stores operating in the area.<sup>5</sup>

Thus, the relevant line of commerce in which to analyze the Acquisition is no narrower than discount general merchandise retail stores. In certain geographic markets, the relevant line of commerce may be as broad as the sale of discounted general merchandise in retail stores (i.e., discount general merchandise retail stores as well as supermarkets, pharmacies, mass merchandisers, and discount specialty merchandise retail stores). Whether the relevant line of commerce is discount general merchandise retail stores or discounted general merchandise in retail stores depends on the specifics of the geographic market at issue, such as population density and the density and proximity of the Respondents' stores and competing retailers.

The relevant geographic market varies depending on the unique characteristics of each market, including the local road network, physical boundaries, and population density. A strong motivation of consumers shopping at discount general merchandise retail stores is convenience. As with grocery shopping, the vast majority of consumers who shop for discounted general merchandise do so at stores located very close to where they live or work. The draw area of a dollar store, which varies depending on whether it is located in an urban, suburban, or rural area, may range from a couple of city blocks to several miles. Other market participants, such as supermarkets and retail pharmacies, may have similar, although somewhat broader draw areas. Walmart's stores, particularly Walmart Supercenters, tend to have a considerably broader draw area. In highly urban areas, the geographic markets are generally no broader than a half-mile radius around a given store. In highly rural areas, the geographic market is generally no narrower than a three-mile radius around a given store. In areas neither highly urban nor highly rural, the geographic market is generally within a half-mile to three-mile radius around a given store.

Respondents are close competitors in terms of format, customer service,

product offerings, and location in the relevant geographic markets. With regard to pricing, product assortment, and a host of other competitive issues, Respondents typically focus most directly on the actions and responses of each other and other dollar stores, while also paying close attention to Walmart. In many of the relevant geographic markets, Dollar Tree and Family Dollar operate the only dollar stores in the area or the vast majority of convenientlylocated discount general merchandise retail stores. Absent relief, the Acquisition would increase the incentive and ability of Dollar Tree to raise prices unilaterally post-Acquisition in the relevant geographic markets. The Acquisition would also decrease incentives to compete on nonprice factors, including product selection, quality, and service.

Entry into the relevant geographic markets that is timely and sufficient to prevent or counteract the expected anticompetitive effects of the Acquisition is unlikely. Entry barriers include the time, costs, and feasibility associated with identifying and potentially constructing an appropriate and available location for a discount general merchandise retail store, the resources required to support one or more new stores over a prolonged rampup period, and the sufficient scale to compete effectively. An entrant's ability to secure a viable competitive location may be hindered by restrictive-use commercial lease covenants, which can limit the products sold, or even the type of retailer that can be located, at a particular location.

#### **IV. The Proposed Consent Order**

The proposed remedy, which requires the divestiture of 330 Family Dollar stores in the relevant markets to Sycamore Partners ("Sycamore"), will restore fully the competition that otherwise would be eliminated in these markets as a result of the Acquisition. Sycamore is a private equity firm specializing in consumer and retail investments. The proposed buyer appears to be a highly suitable purchaser and is well positioned to enter the relevant geographic markets and prevent the likely competitive harm that otherwise would result from the Acquisition. Sycamore's proposed executive team has extensive experience operating discount general merchandise retail stores.

The proposed Consent Order requires Respondents to divest 330 stores to Sycamore within 150 days from the date of the Acquisition. If, at any time before the proposed Consent Order is made final, the Commission determines that Sycamore is not an acceptable buyer, Respondents must immediately rescind the divestitures and divest the assets to a different buyer that receives the Commission's prior approval.

The proposed Consent Order contains additional provisions to ensure the adequacy of the proposed relief. For example, Respondents have agreed to an Order to Maintain Assets that will be issued at the time the proposed Consent Order is accepted for public comment. The Order to Maintain Assets requires Family Dollar to operate and maintain each divestiture store in the normal course of business through the date the store is ultimately divested to Sycamore. Because the divestiture schedule runs for an extended period of time, the proposed Consent Order appoints Gary Smith as a Monitor to oversee Respondents' compliance with the requirements of the proposed Consent Order and Order to Maintain Assets. Mr. Smith has the experience and skills to be an effective Monitor, no identifiable conflicts, and sufficient time to dedicate to this matter through its conclusion.

The sole purpose of this Analysis is to facilitate public comment on the proposed Consent Order. This Analysis does not constitute an official interpretation of the proposed Consent Order, nor does it modify its terms in any way.

#### Appendix A

	City	Number of stores divested
Alabama	Montgomery Lake Havasu Tucson Farmersville Fresno Inglewood Lemoore San Bernardino Aurora Colorado	1 1 1 1 1 1 1 1
Colorado	Springs. Denver	1 1 1 1 1 1 1 1 2 3 3 3

<sup>&</sup>lt;sup>5</sup> Online retailers are not participants in the relevant product market. The primary appeal of dollar stores is the combination of value and convenience they offer consumers. Given the time required to process and ship items ordered online, Internet retailers are less convenient shopping options for consumers looking to make an immediate purchase on a fill-in trip.

		Number			Number			Number
	City	of stores divested		City	of stores divested		City	of stores divested
Florida	Tampa	3	Michigan	Inkster	1	Ohio	East Cleveland	1
Georgia	Atlanta	7	Michigan	Lansing	;	Ohio	Milford	
Georgia	Columbus	1	Michigan	Livonia	l i	Ohio	St. Bernard	l i
Georgia	Decatur	3	Michigan	Mount Morris	;	Ohio	Toledo	2
Georgia	Lake City	1	Michigan	Oak Park		Ohio	Whitehall	1
Georgia	Norcross		Michigan	Portage		Oklahoma	Oklahoma City	2
_ •	Stone Mountain	1		Saginaw	1			1
GeorgiaIdaho	Emmett	1	Michigan Michigan	Taylor	1	Pennsylvania	Allentown East Liberty	1
		1		Westland	1	Pennsylvania		1
Illinois	Aurora	<del>-</del>	Michigan		1	Pennsylvania	Edwardsville	1
Illinois	Berwyn	1	Michigan	Wyoming	1	Pennsylvania	Harrisburg	2
Illinois	Chicago	13	Minnesota	Minneapolis	3	Pennsylvania	Lansdowne	1
Illinois	Elgin	1	Minnesota	Robbinsdale	1	Pennsylvania	Levittown	1
Illinois	Harvey	1	Minnesota	St. Paul	3	Pennsylvania	Mckeesport	1
Indiana	Fort Wayne	1	Mississippi	Jackson	1	Pennsylvania	Middletown	1
Indiana	Gary	2	Missouri	Jennings	1	Pennsylvania	Morrisville	1
Indiana	Indianapolis	2	Missouri	St. Louis	6	Pennsylvania	Philadelphia	5
Kentucky	Covington	1	Nebraska	Omaha	1	Pennsylvania	Pittsburgh	2
Kentucky	Louisville	2	New Jersey	Belmar	1	Pennsylvania	Swissvale	1
Louisiana	Baton Rouge	1	New Jersey	Brigantine	1	Pennsylvania	Upper Darby	1
Louisiana	Lafayette	1	New Jersey	East Orange	1	Pennsylvania	Yeadon	1
Louisiana	New Orleans	1	New Jersey	Elizabeth	2	Rhode Island	Bristol	1
Maine	Caribou	1	New Jersey	Ewing	1	Rhode Island	Central Falls	1
Maine	Gray	1	New Jersey	Glassboro	1	Rhode Island	Pawtucket	2
Maine	Lewiston	1	New Jersey	Hamilton Town-	1	Rhode Island	Providence	2
Maine	Livermore Falls	1		ship.		Rhode Island	Rumford	1
Maine	Old Town	1	New Jersey	Irvington	1	Tennessee	Memphis	3
Maine	South Portland	1	New Jersey	Mount Holly	1	Tennessee	Nashville	1
Maine	Waterville	1	New Jersey	Newark	2	Texas	Arlington	1
Maryland	Baltimore	4	New Jersey	Paterson	1	Texas	Balch Springs	1
Maryland	Capitol Heights	1	New Jersey	Pleasantville	1	Texas	Beaumont	1
Maryland	Lanham	1	New Jersey	Vineland	1	Texas	Brownsville	1
Maryland	Mount Rainier	1	New Mexico	Albuquerque	3	Texas	Corpus Christi	1
Maryland	Oxon Hill	1	New Mexico	Las Cruces	1	Texas	Dallas	1
Maryland	Salisbury	1	New York	Astoria	1	Texas	Eagle Pass	1
Maryland	Silver Spring	1	New York	Bronx	8	Texas	El Paso	3
Maryland	Temple Hills	1	New York	Brooklyn	7	Texas	Fort Worth	2
Massachusetts	Boston	1	New York	College Point	1	Texas	Houston	5
Massachusetts	Brockton	1	New York	East Aurora	1	Texas	Lubbock	1
Massachusetts	Cambridge	1	New York	Far Rockaway	1	Texas	Odessa	1
Massachusetts	Chelsea	1	New York	Glendale	1	Texas	Pasadena	1
Massachusetts	Dorchester	1	New York	Grand Island	1	Texas	San Antonio	2
Massachusetts	Framingham	1	New York	Greece	1	Utah	Midvale	1
Massachusetts	Gloucester	1	New York	Jamaica	2	Utah	Ogden	1
Massachusetts	Greenfield	1	New York	Johnstown	1	Utah	Provo	1
Massachusetts	Holyoke	1	New York	Lindenhurst	1	Utah	Salt Lake City	1
Massachusetts	Lowell	1	New York	Mattydale	1	Utah	St. George	1
Massachusetts	Medford	1	New York	Mount Vernon	1	Utah	West Valley	1
Massachusetts	New Bedford	1	New York	Patchogue	1		City.	
Massachusetts	North Adams	1	New York	Poughkeepsie	1	Vermont	Morrisville	1
Massachusetts	Randolph	1	New York	Queens	2	Vermont	Newport	1
Massachusetts	Revere	1	New York	Queens Village	1	Virginia	Alexandria	1
Massachusetts	South Yar-	1	New York	Ridgewood	1	Virginia	Chesapeake	1
	mouth.		New York	Rochester	3	Virginia	Hampton	1
Massachusetts	Springfield	2	New York	Rocky Point	1	Virginia	Lynchburg	1
Massachusetts	Ware	1	New York	Saranac Lake	1	Virginia	Norfolk	3
Massachusetts	West Spring-	1	New York	Selden	1	Virginia	Portsmouth	1
	field.		New York	Shirley	1	Virginia	Richmond	i
Massachusetts	Worcester	1	New York	Springfield Gar-	1	West Virginia	Huntington	i
Michigan	Benton Harbor	i		dens.		Wisconsin	Appleton	l i
Michigan	Burton	i	New York	Staten Island	2	Wisconsin	Eau Claire	l i
Michigan	Detroit	5	New York	Syracuse	2	Wisconsin	Milwaukee	3
Michigan	Eastpointe	1	New York	Utica	1	Wisconsin	St. Francis	1
Michigan	Ferndale	i	North Carolina	Charlotte	2	- 1000110111	Ct. 1 1411013	<u> </u>
Michigan	Grand Rapids	2	Ohio	Akron	1			
Michigan	Hamtramck	1	Ohio	Canton			f the Commission,	
Michigan	Hazel Park	1	Ohio	Cincinnati	5	Commissioner W	right dissenting.	
wiionigan	I IULUI I air		OI 110	Unioninal	, 5		-	

Cincinnati ......

Cleveland ......

Ohio ...... Columbus ......

Ohio .....

Ohio .....

Hazel Park .....

Highland Park

Michigan ..... Holland .....

Michigan .....

Michigan .....

Donald S. Clark,

<sup>5</sup> 4 Secretary.

#### Statement of the Federal Trade Commission

The Federal Trade Commission has accepted a proposed settlement to resolve the likely anticompetitive effects of Dollar Tree, Inc.'s proposed \$9.2 billion acquisition of Family Dollar Stores, Inc.<sup>1</sup> We have reason to believe that, absent a remedy, the proposed acquisition is likely to substantially lessen competition between Dollar Tree and Family Dollar in numerous local markets. Under the terms of the proposed consent order, Dollar Tree and Family Dollar are required to divest 330 stores to a Commission-approved buyer. As we explain below, we believe the proposed divestitures preserve competition in the markets adversely affected by the acquisition and are therefore in the public interest.

Dollar Tree operates over 5,000 discount general merchandise retail stores across the United States under two banners which follow somewhat different business models. In its Dollar Tree banner stores, Dollar Tree sells a wide selection of everyday basic, seasonal, closeout, and promotional merchandise—all for \$1 or less. At its Deals banner stores, Dollar Tree sells an expanded assortment of this merchandise at prices that may go above the \$1 price point but are generally less than \$10. Family Dollar operates over 8,000 discount general merchandise retail stores. Family Dollar sells an assortment of consumables, home products, apparel and accessories, seasonal items, and electronic merchandise at prices generally less than \$10, including items priced at or under \$1.

Dollar Tree and Family Dollar compete head-to-head in numerous local markets across the United States. They are close competitors in terms of format, pricing, customer service, product offerings, and location. When making competitive decisions regarding pricing, product assortment, and other salient aspects of their businesses, Dollar Tree and Family Dollar focus most directly on the actions and responses of each other and other "dollar store" chains, while also paying close attention to Walmart. In many local markets, Dollar Tree and Family Dollar operate stores in close proximity to each other, often representing the only or the majority of conveniently located discount general merchandise

retail stores in a neighborhood.

To evaluate the likely competitive effects of this transaction and identify

the local markets where it may likely harm competition, the Commission considered multiple sources of quantitative and qualitative evidence. One component of the investigation involved a Gross Upward Pricing Pressure Index ("GUPPI") analysis. As described in the 2010 Horizontal Merger Guidelines, this mode of analysis can serve as a useful indicator of whether a merger involving differentiated products is likely to result in unilateral anticompetitive effects.<sup>2</sup> Such effects can arise "when the merger gives the merged entity an incentive to raise the price of a product previously sold by one merging firm" because the merged entity stands to profit from any sales that are then diverted to products that would have been "previously sold by the other merging firm." 3 Using the value of diverted sales as an indicator of the upward pricing pressure resulting from the merger, a GUPPI is defined as the value of diverted sales that would be gained by the second firm measured in proportion to the revenues that would be lost by the first firm. If the "value of diverted sales is proportionately small, significant unilateral price effects are unlikely."4

The Commission's investigation involved thousands of Dollar Tree and Family Dollar stores with overlapping geographic markets. A GUPPI analysis served as a useful initial screen to flag those markets where the transaction might likely harm competition and those where it might pose little or no risk to competition. As a general matter, Dollar Tree and Family Dollar stores with relatively low GUPPIs suggested that the transaction was unlikely to harm competition, unless the investigation uncovered specific reasons why the GUPPIs may have understated the potential for anticompetitive effects. Conversely, Dollar Tree and Family Dollar stores with relatively high GUPPIs suggested that the transaction was likely to harm competition, subject to evidence or analysis indicating that the GUPPIs may have overstated the potential for anticompetitive effects.

While the GUPPI analysis was an important screen for the Commission's inquiry, it was only a starting point. The Commission considered several other sources of evidence in assessing the transaction's likely competitive effects, including additional detail regarding the geographic proximity of the merging parties' stores relative to each other and

to other retail stores, ordinary course of business documents and data supplied by Dollar Tree and Family Dollar, information from other market participants, and analyses conducted by various state attorneys general who were also investigating the transaction. After considering all of this evidence, the Commission identified specific local markets where the acquisition would be likely to harm competition and arrived at the list of 330 stores slated for divestiture.

In his statement, Commissioner Wright criticizes the way that the Commission used the GUPPI analysis in this case and argues that GUPPIs below a certain threshold should be treated as a "safe harbor." <sup>5</sup> We respectfully disagree.

As an initial matter, Commissioner Wright mischaracterizes the way that the GUPPI analysis was used in this case. Contrary to his suggestion, GUPPIs were not used as a rigid presumption of harm. As explained above, they were used only as an initial screen to identify those markets where further investigation was warranted. The Commission then proceeded to consider the results of the GUPPI analysis in conjunction with numerous other sources of information.<sup>6</sup> Based on this complete body of evidence, we have reason to believe that, without the proposed divestitures, the acquisition would substantially lessen competition in each of the relevant local markets.

Our market-by-market review showed that the model of competition underlying the GUPPI analysis was largely consistent with other available evidence regarding the closeness of competition between the parties' stores in each local market. For example, stores with high GUPPIs were generally found in markets in which there were few or no other conveniently located discount general merchandise retail stores. The GUPPI analysis did have some limitations, however. For example, there were Family Dollar stores with relatively low GUPPIs in markets that were nevertheless pricezoned to Dollar Tree stores, which meant that if Dollar Tree stores were

<sup>&</sup>lt;sup>1</sup> This statement reflects the views of Chairwoman Ramirez and Commissioners Brill, Ohlhausen, and McSweeny.

<sup>&</sup>lt;sup>2</sup> U.S. Dept. of Justice and Fed. Trade Comm'n, Horizontal Merger Guidelines § 6.1 (2010), available at https://www.ftc.gov/sites/default/files/ attachments/merger-review/100819hmg.pdf.

 $<sup>^3</sup>$  Id.

<sup>4</sup> Id.

<sup>&</sup>lt;sup>5</sup> Statement of Commissioner Joshua D. Wright Dissenting in Part and Concurring in Part, *Dollar Tree, Inc. and Family Dollar Stores, Inc.*, File No. 141–0207.

<sup>&</sup>lt;sup>6</sup> As Joseph Farrell and Carl Shapiro have noted, "[r]eal-world mergers are complex, and our proposed test, like the concentration-based test, is consciously oversimplified. . . In the end, the evaluation of any merger that is thoroughly investigated or litigated may come down to the fullest feasible analysis of effects." Joseph Farrell & Carl Shapiro, Antitrust Evaluation of Horizontal Mergers: An Economic Alternative to Market Definition, 10 B.E. J. Theoretical Econ. 1, 26 (2010).

removed as competition, then the prices of certain items at those Family Dollar stores would likely go up. The GUPPI analysis also was not sufficiently sensitive to differentiate between Dollar Tree and Family Dollar stores that were in the same shopping plaza from those that were almost a mile away from each other. For these situations, we appropriately relied on other evidence to reach a judgment about the closeness of competition.<sup>7</sup>

More broadly, Commissioner Wright's view that the Commission should identify and treat GUPPIs below a certain threshold as a "safe harbor" ignores the reality that merger analysis is inherently fact-specific. The manner in which GUPPI analysis is used will vary depending on the factual circumstances, the available data, and the other evidence gathered during an investigation. Moreover, whether the value of diverted sales is considered "proportionately small" compared to lost revenues will vary from industry to industry and firm to firm.8 For example, intense competition between merging firms may cause margins to be very low, which could produce a low GUPPI even in the presence of very high diversion ratios. Such conditions could produce a false negative implying that the merger is not likely to harm competition when in fact it is.9

Indeed, we agree with Commissioner Wright that "a GUPPI-based presumption of competitive harm is inappropriate at this stage of economic learning." <sup>10</sup> We think that a GUPPI-based safe harbor is equally inappropriate. In antitrust law, brightline rules and presumptions rest on accumulated experience and economic learning that the transaction or conduct in question is likely or unlikely to harm competition. <sup>11</sup> We do not believe there

is a basis for the recognition of a GUPPI safe harbor.

Accordingly, in any case where a GUPPI analysis is used, the Commission will consider the particular factual circumstances and evaluate other sources of quantitative and qualitative evidence. 12 As with other quantitative evidence such as market shares and HHIs, we believe that GUPPIs should be considered in the context of all other reasonably available evidence. The 2010 Horizontal Merger Guidelines do not instruct otherwise.13 For all of these reasons, we believe it is appropriate to use GUPPIs flexibly and as merely one tool of analysis in the Commission's assessment of unilateral anticompetitive effects.

By direction of the Commission, Commissioner Wright not participating.

consequence, the per se rule is appropriate only after courts have had considerable experience with the type of restraint at issue, . . . and only if courts can predict with confidence that it would be invalidated in all or almost all instances under the rule of reason, . . . "); Cal. Dental Ass'n v. FTC, 526 U.S. 756, 781 (1999) ("The object is to see whether the experience of the market has been so clear, or necessarily will be, that a confident conclusion about the principal tendency of a restriction will follow from a quick (or at least quicker) look, in place of a more sedulous one."); ProMedica Health Sys., Inc. v. FTC, 749 F.3d 559, 570, 571 (6th Cir. 2014) (noting that "the strong correlation between market share and price, and the degree to which this merger would further concentrate markets that are already highly concentrated—converge in a manner that fully supports the Commission's application of a presumption of illegality" but also noting that "the Commission did not merely rest upon the presumption, but instead discussed a wide range of evidence that buttresses it").

12 See Carl Shapiro, The 2010 Horizontal Merger Guidelines: From Hedgehog to Fox in Forty Years, 77 Antitrust L.J. 701, 729 (2010) ("The value of diverted sales is an excellent simple measure for diagnosing or scoring unilateral price effects, but it cannot capture the full richness of competition in real-world industries. Indeed, as stressed above, all of the quantitative methods discussed here must be used in conjunction with the broader set of qualitative evidence that the Agencies assemble during a merger investigation."); Farrell & Shapiro, Upward Pricing Pressure, supra note 8, at 6 ("Whatever measure is used for screening purposes, it is important that the full analysis give proper weight to all the available evidence."). Notwithstanding Commissioner Wright's suggestion to the contrary, we do not believe that the Commission's use of GUPPIs as a tool for assessing unilateral effects differs materially from their use by the Department of Justice.

 $^{13}$  Recognizing in the 2010 Horizontal Merger Guidelines that when the ''value of diverted sales is proportionately small, significant unilateral price effects are unlikely" does not necessarily mean that "proportionately small" should be reduced to some numerical value that applies in all cases. See Merger Guidelines, supra note 2,  $\S$  1 (''These Guidelines should be read with the awareness that merger analysis does not consist of uniform application of a single methodology.'').

## Statement of Commissioner Joshua D. Wright Dissenting in Part and Concurring in Part

The Commission has voted to issue a Complaint and a Decision & Order against Dollar Tree, Inc. ("Dollar Tree") and Family Dollar Stores, Inc. ("Family Dollar") to remedy the allegedly anticompetitive effects of the proposed acquisition by Dollar Tree of Family Dollar. I dissent in part from and concur in part with the Commission's decision. I dissent in part because in 27 markets I disagree with the Commission's conclusion that there is reason to believe the proposed transaction violates the Clayton Act.

The record evidence includes a quantitative measure of the value of diverted sales as well as various forms of qualitative evidence. The value of diverted sales is typically measured as the product of the diversion ratio between the merging parties' products the diversion ratio between two products is the percentage of unit sales lost by one product when its price rises, that are captured by the second product—and the profit margin of the second product. When the value of diverted sales is measured in proportion to "the lost revenues attributable to the reduction in unit sales resulting from the price increase," 1 it is the "gross upward pricing pressure index," or "GUPPI." The GUPPI is an economic tool used to score or rank the incentives for potential unilateral price effects. In the markets where I depart from the Commission's decision the GUPPI is below 5 percent, indicating insignificant upward pricing pressure even before efficiencies or entry are taken into account, and weak incentives for unilateral price increases. In my view, the available quantitative and qualitative evidence are insufficient to support a reason to believe the proposed transaction will harm competition in these markets. I write separately to explain more fully the basis for my dissent in these markets.

I also write to address an important merger policy issue implicated by today's decision—that is, whether the FTC should adopt a safe harbor in unilateral effects merger investigations by defining a GUPPI threshold below which it is presumed competitive harm is unlikely. The Merger Guidelines clearly contemplate such a safe harbor. The Merger Guidelines explain that "[i]f the value of diverted sales is proportionately small, significant

<sup>&</sup>lt;sup>7</sup> Commissioner Wright cites the Albertson's/ Safeway transaction as another recent case in which a GUPPI analysis was used. *See* Wright Statement at 2 n.6. To be precise, the Commission analyzed that transaction using diversion ratios, not GUPPI scores, but in any event, Commissioner Wright himself voted to accept the consent order in that

<sup>&</sup>lt;sup>8</sup> Marginal cost efficiencies, as well as passthrough rates, also will vary from industry to industry and from firm to firm. The pass-through rate will determine the magnitude of the postmerger unilateral price effects.

<sup>&</sup>lt;sup>9</sup> Joseph Farrell & Carl Shapiro, *Upward Pricing Pressure and Critical Loss Analysis: Response*, CPI Antitrust J. 1, 6–7 & n.15 (Feb. 2010); Farrell & Shapiro, *Antitrust Evaluation of Horizontal Mergers, supra* note 6, at 13–14.

<sup>&</sup>lt;sup>10</sup>Wright Statement, *supra* note 5, at 8 & nn.23 & 24 (citing commentators' concerns and criticisms regarding the use of GUPPI analysis generally). Such concerns and criticisms, if valid, would apply equally to the wisdom of using GUPPIs to recognize a safe harbor.

<sup>&</sup>lt;sup>11</sup> See, e.g., Leegin Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 886–87 (2007) ("As a

<sup>&</sup>lt;sup>1</sup> U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines § 6.1 n.11 (2010) [hereinafter Merger Guidelines].

unilateral price effects are unlikely." <sup>2</sup> In other words, the *Merger Guidelines* recognize that if the GUPPI is small, significant unilateral price effects are unlikely.

Without more, one might reasonably conclude it is unclear whether the Merger Guidelines merely offer a truism about the relationship between the GUPPI and likely unilateral price effects or invite the agencies to take on the task of identifying a safe harbor of general applicability across cases. But there is more. A principal drafter of the Merger Guidelines has explained the Merger Guidelines' reference to a 'proportionately small'' value of diverted sales was intended to establish a GUPPI safe harbor. The Department of Iustice's Antitrust Division ("Division"). consistent with this interpretation of the Merger Guidelines, publicly announced precisely such a safe harbor when the GUPPI is less than 5 percent.<sup>3</sup> Further, there is significant intellectual support for a GUPPI-based safe harbor among economists 4—once again including the principal drafters of the Merger Guidelines. The Commission, however, has rejected the safe harbor approach both in practice—indeed, the Commission has recently entered into another consent involving divestitures in markets with GUPPI scores below 5 percent 6—and as a matter of the policy

announced in the Commission's statement today.<sup>7</sup>

This is unfortunate. The legal, economic, and policy case for the GUPPI-based safe harbor contemplated by the *Merger Guidelines* is strong.<sup>8</sup> There are a number of reasons why such a safe harbor might be desirable as a matter of antitrust policy if sufficiently supported by economic theory and evidence. Efficient resource allocation—expending agency resources on the transactions most likely to raise serious competitive concerns and quickly dispensing with those that do not—is one such goal.

A second reason a safe harbor for proportionately small diversion might be desirable antitrust policy is to compensate for the sources of downward pricing pressure not measured by the GUPPI but expected with most transactions, including efficiencies, entry, or repositioning. Some have argued that—as a GUPPI

diversion or GUPPI-based analysis was a step forward relative to relying exclusively upon structural analysis. The fact that there were stores identified for divestiture with implied GUPPIs less than 5 percent was unique. It is now a trend reinforced by a Commission decision to reject a GUPPI-based safe harbor—a decision I do not believe is in the public interest.

Regarding Cerberus, it is worth pointing out further that even a careful reader of the public documents in that case would come away with the impression that the Commission's analysis was largely structural, and concluded a number of sixto-five mergers were presumptively anticompetitive. See Analysis of Agreement Containing Consent Order to Aid Public Comment Exhibit A, id. An ancillary benefit of the transparency reluctantly generated by today's Commission statement is that the antitrust community is now on notice that more sophisticated economic tools were used in that matter, how they were used, and that the potential structural policy change signaled by those public documents does not appear to describe accurately the Commission's complete analysis in that case.

<sup>7</sup> Statement of the Federal Trade Commission at 3, Dollar Tree, Inc., FTC File No. 141–0207 (July 13, 2015) [hereinafter Majority Statement] ("[A] GUPPI-based safe harbor is . . . inappropriate.").

<sup>8</sup> A second question is whether a presumption of competitive harm should follow, as a matter of economic theory and empirical evidence, from a demonstration of a GUPPI above a certain threshold value. There appears to be a consensus that the answer to this question, at this point, is no. I agree. See, e.g., Thomas A. Lambert, Respecting the Limits of Antitrust: The Roberts Court Versus the Enforcement Agencies 13 (Heritage Foundation Legal Memorandum No. 144, Jan. 28, 2015) (the GUPPI "has not been empirically verified as a means of identifying anticompetitive mergers"); Steven C. Salop, The Evolution and Vitality of Merger Presumptions: A Decision-Theoretic Approach 40–41 (Georgetown Law Faculty Publications and Other Works, Working Paper No. 1304, 2014), available at http:// scholarship.law.georgetown.edu/facpub/1304/ ("The 2010 Merger Guidelines do not adopt an anticompetitive enforcement presumption based on high values of the GUPPI score. This was a practical policy decision at this time because the use of the GUPPI was new to much of the defense bar and the courts.").

attempts a rough measure of upward pricing pressure without a full blown analysis—a symmetrical approach would include a standard efficiencies deduction which would be applied to account for the downward pricing pressure from the marginal-cost efficiencies that can typically be expected to result from transactions. This approach would permit the identification of a gross-upward-pricing-pressure threshold that triggers additional scrutiny. 10

Yet a third reason a safe harbor might be desirable is to compensate the wellknown feature of GUPPI-based scoring methods to predict harm for any positive diversion ratio—that is, even for distant substitutes—by distinguishing de minimis GUPPI levels from those that warrant additional scrutiny. 11 The Merger Guidelines contemplate a "safe harbor" because it "reflects that a small amount of upward pricing pressure is unlikely . . .  $\bar{\text{to}}$ correspond to any actual post-merger price increase." 12 Carl Shapiro explained shortly after adoption of the Merger Guidelines, on behalf of the Division, that "Current Division practice is to treat the value of diverted sales as proportionately small if it is no more than 5% of the lost revenues." 13

Against these benefits of adopting a GUPPI-based safe harbor, the Commission must weigh the cost of reducing its own flexibility and prosecutorial discretion. This begs the question: How likely are mergers within the proposed safe harbor to be anticompetitive? The benefits of this flexibility are proportional to the probability that the Commission's economic analysis leads them to conclude that mergers with a GUPPI of less than 5 percent are anticompetitive. I am not aware of any transactions since

<sup>&</sup>lt;sup>2</sup> Id. § 6.1 (emphasis added); see Steven C. Salop, Serge X. Moresi & John Woodbury, CRA Competition Memo, Scoring Unilateral Effects with the GUPPI: The Approach of the New Horizontal Merger Guidelines 2 (Aug. 31, 2010), available at http://crai.com/sites/default/files/publications/Commentary-on-the-GUPPI\_0.pdf.

<sup>&</sup>lt;sup>3</sup> Carl Shapiro, Deputy Ass't Att'y Gen. for Econ., Antitrust Div., U.S. Dep't of Justice, Update from the Antitrust Division, Remarks as Prepared for the ABA Antitrust Law Fall Forum 24 (Nov. 18 2010).

<sup>&</sup>lt;sup>4</sup> See, e.g., Salop, Moresi & Woodbury, supra note 2, at 2 (explaining that "a GUPPI of less than 5% would be reasonably treated as evidence that 'the value of diverted sales is proportionately small' and hence that the proposed merger is unlikely to raise unilateral effects concerns").

<sup>&</sup>lt;sup>5</sup> See Joseph Farrell & Carl Shapiro, Antitrust Evaluation of Horizontal Mergers: An Economic Alternative to Market Definition, 10 B.E. J. Theoretical Econ. 1 (2010).

<sup>&</sup>lt;sup>6</sup> See Cerberus Institutional Partners V. L.P., FTC File No. 141-0108 (July 2, 2015). There, though one could not possibly infer this from the public-facing documents in the case, the Commission applied a diversion ratio threshold to identify stores for divestiture. To be accurate, a GUPPI threshold could be implied from the Commission's analysis and, as algebraically mindful readers will note, setting a diversion ratio threshold given profit margin data and a predicted price increase is not analytically distinguishable from the analysis in this matter. The Commission rightly points out that I voted in favor of the consent in Cerberus. As to whether I am merely being inconsistent in my views on the role of GUPPIs in merger analysis or, alternatively, there is some other more reasonable explanation for my votes, I can provide the explanation and let readers decide. In Cerberus, I voted for the consent on the basis that the use of

<sup>&</sup>lt;sup>9</sup> Farrell & Shapiro, *supra* note 5, at 10–12. <sup>10</sup> See id. at 12.

<sup>&</sup>lt;sup>11</sup> James A. Keyte & Kenneth B. Schwartz, "Tally-Ho!": UPP and the 2010 Horizontal Merger Guidelines, 7 Antitrust L.J. 587, 628 (2010) ("an uncalibrated tool cannot have predictive value as a screen if it always indicates postmerger price pressure").

<sup>12</sup> Shapiro, *supra* note 3, at 24. Shapiro further cautioned that, although a GUPPI analysis "can be highly informative, the Agencies understand full well that measuring upward pricing pressure . . . typically is not the end of the story . . . . Repositioning, entry, innovation, and efficiencies must also be considered." *Id.* at 26.

<sup>13</sup> Id. at 24. Others have interpreted this speech as clearly announcing Division policy. See Salop, supra note 8, at 43 & n.105 ("In a speech while he was Deputy AAG, Carl Shapiro also specified a GUPPI safe harbor of 5%. As a speech by the Deputy AAG, this statement appeared to reflect DOJ policy." (citing Shapiro, supra note 3)). Other economists agree that a GUPPI safe harbor should apply. E.g., Farrell & Shapiro, supra note 5, at 10; Salop, Moresi & Woodbury, supra note 2, at 2.

the *Merger Guidelines* were adopted other than the two already mentioned that meet these criteria. The domain in which flexibility would be reduced with adoption of a reasonable safe harbor is small and the costs of doing so correspondingly low.

The Commission rejects a GUPPI safe harbor on the grounds that such an approach "ignores the reality that merger analysis is inherently factspecific." 14 The Commission appears especially concerned that a GUPPIbased safe harbor might result in a false negative-that is, it is possible that a merger with a GUPPI less than 5 percent harms competition. This objection to safe harbors and bright-line rules and presumptions is both conceptually misguided and is in significant tension with antitrust doctrine and agency practice. Merger analysis is, of course, inherently fact specific. One can accept that reality, as well as the reality that evidence is both imperfect and can be costly to obtain, and yet still conclude that the optimal legal test from a consumer welfare perspective is a rule rather than a standard. This is a basic insight of decision theory, which provides a lens through which economists and legal scholars have long evaluated antitrust legal rules, burdens, and presumptions.<sup>15</sup> The Commission's assertion that the mere possibility of false negatives undermines in the slightest the case for a safe harbor reveals a misunderstanding of the economic analysis of legal rules. The relevant question is not which legal rule drives false positives or false negatives to zero, but rather which legal rule minimizes the sum of the welfare costs associated with false negatives, false positives, and the costs of obtaining evidence and otherwise administering

Existing antitrust law regularly embraces bright-line rules and presumptions—rejecting the flexibility of a case-by-case standard taking full account of facts that vary across industries and firms. A simple example

is the application of per se rules in price-fixing cases. 16 This presumption of illegality is not based upon a belief that it is impossible for a horizontal restraint among competitors to increase welfare. Rather, the per se prohibition on naked price fixing "reflects a judgment that the costs of identifying exceptions to the general rule so far outweigh the costs of occasionally condemning conduct that might upon further inspection prove to be acceptable, that it is preferable not to entertain defenses to the conduct at all." 17 Similar decision-theoretic logic explains, for example, the presumption that above-cost prices are lawful. 18 A GUPPI-based presumption would be based upon the same economic logicnot that small-GUPPI mergers can never result in anticompetitive effects, but rather that mergers involving small GUPPIs are sufficiently unlikely to result in unilateral price increases such that incurring the costs of identifying exceptions to the safe harbor is less efficient than simply allowing mergers

within the safe harbor to move forward.<sup>19</sup>

Whether the Commission should adopt a GUPPI-based safe harbor is particularly relevant in the instant matter, as the FTC had data sufficient to calculate GUPPIs for Dollar Tree, Deals,<sup>20</sup> and Family Dollar stores. The sheer number of stores owned and operated by the parties rendered individualized, in-depth analysis of the competitive nuances of each and every market difficult, if not impossible, to conduct. GUPPI calculations provided an efficient and workable alternative to identifying the small fraction of markets in which the transaction may be anticompetitive. This was a tremendous amount of work and I want to commend staff on taking this approach. Staff identified a GUPPI threshold such that stores with GUPPIs greater than the threshold were identified for divestiture. About half of the 330 stores divested as part of the Commission's Order were identified through this process.

What about the other stores? The Commission asserts I "mischaracterize[]" its use of GUPPIs and that "GUPPIs were not used as a rigid presumption of harm." <sup>21</sup> It claims that GUPPIs were used only as "an initial screen" to identify markets for further analysis, and that the Commission "proceeded to consider the results of the GUPPI analysis in conjunction with numerous other sources of information." <sup>22</sup> The evidence suggests otherwise. One might reasonably hypothesize that further consideration and analysis of

<sup>&</sup>lt;sup>14</sup> Majority Statement, supra note 7, at 3. <sup>15</sup> See, e.g., C. Frederick Beckner III & Steven C. Salop, Decision Theory and Antitrust Rules, 67 Antitrust L.J. 41 (1999); James C. Cooper, Luke M. Froeb, Dan O'Brien & Michael G. Vita, Vertical Antitrust Policy as a Problem of Inference, 23 Int'l J. Indus. Org. 639 (2005); Frank H. Easterbrook, The Limits of Antitrust, 63 Tex. L. Rev. 1 (1984); Isaac Ehrlich & Richard A. Posner, An Economic Analysis of Legal Rulemaking, 3 J. Legal Stud. 257 (1974); David S. Evans & A. Jorge Padilla, Designing Antitrust Rules for Assessing Unilateral Practices: A Neo-Chicago Approach, 72 U. Chi. L. Rev. 27 (2005); Keith N. Hylton & Michael Salinger, Tying Law and Policy: A Decision Theoretic Approach, 69 Antitrust L.J. 469 (2001); Geoffrey A. Manne & Joshua D. Wright, Innovation and the Limits of Antitrust, 6 J. Comp. L. & Econ. 153 (2010).

<sup>&</sup>lt;sup>16</sup> See Broad. Music, Inc. v. Columbia Broad. Sys., Inc., 441 U.S. 1, 19–20 (1979) ("More generally, in characterizing this conduct under the per se rule, our inquiry must focus on . . . whether the practice facially appears to be one that would always or almost always tend to restrict competition and decrease output.").

<sup>17</sup> Andrew I. Gavil, William E. Kovacic & Jonathan B. Baker, Antitrust Law in Perspective: Cases, Concepts and Problems in Competition Policy 104-05 (2d ed. 2008); see Barry Wright Corp. v. ITT Grinnell Corp., 724 F.2d 227, 234 (1st Cir. 1983) ("Rules that seek to embody every economic complexity and qualification may well, through the vagaries of administration, prove counterproductive, undercutting the very economic ends they seek to serve. Thus, despite the theoretical possibility of finding instances in which horizontal price fixing, or vertical price fixing, are economically justified, the courts have held them unlawful per se, concluding the administrative virtues of simplicity outweigh the occasional 'economic' loss."); Herbert Hovenkamp, The Antitrust Enterprise: Principle and Execution 50 (2005) ("[N]ot every anticompetitive practice can be condemned."); Thomas A. Lambert, Book Review, Tweaking Antitrust's Business Model, 85 Tex. L. Rev. 153, 172 (2006) ("Hovenkamp's discussion of predatory and limit pricing reflects a key theme that runs throughout The Antitrust Enterprise: That antitrust rules should be easily administrable, even if that means they must permit some anticompetitive practices to go unpunished.").

 $<sup>^{18}\,</sup>See$  Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 226 (1993); see also Barry Wright Corp., 724 F.2d at 234 ("Conversely, we must be concerned lest a rule or precedent that authorizes a search for a particular type of undesirable pricing behavior end up by discouraging legitimate price competition. . . . [A] price cut that ends up with a price exceeding total cost—in all likelihood a cut made by a firm with market power-is almost certainly moving price in the 'right' direction (towards the level that would be set in a competitive marketplace). The antitrust laws very rarely reject such 'birds in hand' for the sake of more speculative (future low-price) 'birds in the bush.' To do so opens the door to similar speculative claims that might seek to legitimate even the most settled unlawful practices.").

 $<sup>^{19}</sup>$  The Commission asserts that a GUPPI safe harbor cannot be justified by economic theory and evidence unless a presumption of liability can also be supported. I appreciate the Commission clarifying its view, but I believe it to be based upon a false equivalence. The Commission appears to misunderstand the difference between evidence sufficient to conclude harm is likely and evidence sufficient to conclude harm is unlikely. These are two very different economic propositions and it should not be surprising that one might be substantiated while the other is not. For example, one might rationally be uncomfortable pointing to the economic literature for support that mergers above a certain level of concentration are sufficiently likely to harm competition to support a presumption of antitrust liability, but also recognize the same body of economic theory and evidence would indeed support a safe harbor for mergers involving markets with thousands of competitors. To the extent the Commission appeals to academics who have raised concerns with GUPPI-based merger screens, my view clearly differs from the Commission. The Commission's more important dispute, in my view, is with the Merger Guidelines and its principal drafters, who clearly contemplated such a safe harbor.

<sup>&</sup>lt;sup>20</sup> Deals is a separate banner under which Dollar Tree operates. *See* Majority Statement, *supra* note 7, at 1.

<sup>21</sup> Id. at 2.

<sup>&</sup>lt;sup>22</sup> *Id*.

"numerous sources of information" should result in both the identification of some stores above the GUPPI threshold that were ultimately determined unlikely to harm competition as well as some stores with GUPPIs below the threshold that nonetheless did create competitive problems—that is, further scrutiny might reveal both false negatives and false positives.

The number of stores with GUPPIs exceeding the identified threshold that, after evaluation in conjunction with the qualitative and other evidence described by the Commission, were not slated for divestiture is nearly zero. This outcome is indistinguishable from the application of a presumption of competitive harm. The additional stores with GUPPIs below the threshold that were then identified for divestiture based upon additional qualitative factors included a significant number of stores with GUPPIs below 5 percent. The ratio of stores falling below the GUPPI threshold but deemed problematic after further qualitative evidence is taken into account to stores with GUPPIs above the threshold but deemed not to raise competitive problems after qualitative evidence is accounted for is unusual and remarkably high. It is difficult to conceive of a distribution of qualitative and other evidence occurring in realworld markets that would result in this ratio. Qualitative evidence should not be a one-way ratchet confirming the Commission's conclusion of likely anticompetitive effects when GUPPIs are high and providing an independent basis for the same conclusion when GUPPIs are low.

I applaud the FTC for taking important initial steps in applying more sophisticated economic tools in conducting merger analysis where the data are available to do so. Scoring metrics for evaluating incentives for unilateral price increases are no doubt a significant improvement over simply counting the number of firms in markets pre- and post-transaction. To be clear, it bears repeating that I agree that a GUPPI-based presumption of competitive harm is inappropriate at this stage of economic learning.<sup>23</sup> There

is no empirical evidence to support the use of GUPPI calculations in merger analysis on a standalone basis, let alone the use of a particular GUPPI threshold to predict whether a transaction is likely to substantially harm competition.<sup>24</sup> I also agree that in the context of a fullscale evaluation of whether a proposed transaction is likely to harm competition, GUPPI-based analysis can and should be interpreted in conjunction with all other available quantitative and qualitative evidence. The relevant policy question is a narrow one: Whether there exists a GUPPI threshold below which the Commission should presumptively conclude a proposed transaction is unlikely to violate the antitrust laws.

The FTC has not publicly endorsed a GUPPI-based safe harbor of 5 percent and disappointingly, has rejected the concept in its statement today. The Commission's interpretation is that what is a "proportionately small" value of diverted sales should vary according to the industry—and even the individual firms—in a given investigation.<sup>25</sup> As discussed, I believe this interpretation contradicts the letter and spirit of the Merger Guidelines.26 Moreover, the Commission's apparent discomfort with safe harbors on the grounds that they are not sufficiently flexible to take into account the factintensive nature of antitrust analysis in any specific matter is difficult to reconcile with its ready acceptance of presumptions and bright-line rules that trigger liability.27

generate many false condemnations of mergers that are, on the whole, beneficial.").

Once it is understood that a safe harbor should apply, it becomes obvious that, for the safe harbor to be effective, the threshold should not move. As the plane crash survivors in LOST can attest, a harbor on an island that cannot be found and that can be moved at will is hardly "safe."  $^{28}$ 

In my view, the Commission should adopt a GUPPI-based safe harbor in unilateral effects investigations where data are available. While reasonable minds can and should debate the optimal definition of a "small" GUPPI, my own view is that 5 percent is a reasonable starting point for discussion. Furthermore, failure to adopt a safe harbor could raise concerns about the potential for divergence between Commission and Division policy in unilateral effects merger investigations.<sup>29</sup> What would be most problematic, however, is if, rather than moving toward a GUPPI-based safe harbor, the FTC were to use GUPPI thresholds to employ a presumption of competitive harm.<sup>30</sup>

in concentration and number of firms pre- and postmerger); Statement of the Federal Trade Commission, ZF Friedrichshafen AG, FTC File No. 141-0235 (May 8, 2015) (finding liability based upon number of firms pre- and post-merger); Mem. in Supp. of Pl. Federal Trade Commission's Mot. for T.R.O. and Prelim. Inj. at 23, FTC, v. Sysco Corp. 2015 WL 1501608, No. 1:15-cv-00256 (D.D.C. 2015) (arguing that the proposed merger was presumptively unlawful based upon the holding of United States v. Phila. Nat'l Bank, 374 U.S. 321 (1963)). That the Commission's tolerance of presumptions that that satisfy its own prima facie burden does not extend to safe harbors raises basic questions about the symmetry of the burdens applied in its antitrust analysis. See Dissenting Statement of Commissioner Joshua D. Wright 6, Ardagh Group S.A., FTC File No. 131-0087 (June 18, 2014) ("[S]ymmetrical treatment in both theory and practice of evidence proffered to discharge the respective burdens of proof facing the agencies and merging parties is necessary for consumer-welfare based merger policy.").

<sup>28</sup> Move the Island, *LOST—Move the Island*, YouTube (Nov. 17, 2008), https://www.youtube.com/watch?v=Fa57rVkLal4.

<sup>29</sup>I do not take a position as to how the Division currently uses the GUPPI analysis. *But see* Majority Statement, *supra* note 7, at 4 n.12. However, public statements by the Division and the Commission—the only sources upon which business firms and the antitrust bar can rely—suggest there are material differences. *Compare id.* at 3 ("IW] hether the value of diverted sales is considered 'proportionately small' compared to lost revenues will vary from industry to industry and firm to firm.") *with* Shapiro, *supra* note 3, at 24 ("Current Division practice is to treat the value of diverted sales as proportionately small if it is no more than 5% of the lost revenues.").

<sup>30</sup> A GUPPI-based safe harbor of the type endorsed by the *Merger Guidelines* implies a GUPPI above the threshold is necessary but not sufficient for liability. A GUPPI-based presumption of harm implies a GUPPI above the threshold is sufficient but not necessary for liability. Unfortunately, the use of GUPPIs here is more consistent with the latter than the former.

<sup>&</sup>lt;sup>23</sup> Joseph J. Simons & Malcolm B. Coate, Upward Pressure on Price Analysis: Issues and Implications for Merger Policy, 6 Eur. Competition J. 377, 389 (2010) (the upward pricing pressure screen "identifies as potentially problematic far more mergers than would be challenged or even investigated under the enforcement standards that have existed for more than twenty years"); Lambert, supra note 8, at 13 ("In the end, the agencies" reliance on the difficult-to-administer, empirically unverified, and inherently biased GUPPI is likely to

<sup>&</sup>lt;sup>24</sup> See Dennis W. Carlton, Revising the Horizontal Merger Guidelines, 10 J. Competition L. & Econ. 1, 7 (2010) ("Perhaps most importantly, UPP [as described in the 2010 Merger Guidelines] is new and little empirical analysis has been performed to validate its predictive value in assessing the competitive effects of mergers."); Keyte & Schwartz, supra note 11, at 590 (discussing the 2010 Merger Guidelines' inclusion of the GUPPI and opining that "in light of the [its] extremely light judicial record, as well as the absence of demonstrated reliability in predicting real-world competitive effects, we think it is premature, at best, to embrace [it] as a screening tool for merger review"); Simons & Coate, supra note 23 ("Because screening mechanisms [such as the GUPPI] purport to highlight general results, they need empirical support to show the methodology actually predicts concerns relatively well. This empirical support is not available at this time."): Lambert, supra note 8, at 13 (the GUPPI "has not been empirically verified as a means of identifying anticompetitive mergers").

<sup>&</sup>lt;sup>25</sup> Majority Statement, supra note 7, at 3.

<sup>&</sup>lt;sup>26</sup> See supra text accompanying note 12.

<sup>&</sup>lt;sup>27</sup> For example, the Commission regularly applies such presumptions of liability involving the number of firms in a market, or presumptions based upon increased market concentration as articulated by the *Merger Guidelines* or the courts. *See*, *e.g.*, Statement of the Federal Trade Commission, Holcim Ltd., FTC File No. 141–0129 (May 8, 2015) (finding liability based upon, alternatively, changes

For these reasons, I dissent in part from and concur in part with the Commission's decision.

[FR Doc. 2015–17767 Filed 7–17–15; 8:45 am] BILLING CODE 6750–01–P

#### **DEPARTMENT OF DEFENSE**

## GENERAL SERVICES ADMINISTRATION

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0054]; [Docket 2015-0053; Sequence 3]

#### Submission to OMB for Review; Federal Acquisition Regulation; U.S.-Flag Air Carriers Statement

**AGENCY:** Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve a previously approved information collection requirement concerning U.S. Flag Air Carriers Statement. A notice was published in the Federal Register at 80 FR 15789 on March 25, 2015. No comments were received.

**DATES:** Submit comments on or before August 19, 2015.

ADDRESSES: Submit comments identified by Information Collection 9000–0054, U.S. Flag Air Carriers Statement by any of the following methods:

- Regulations.gov: http://
  www.regulations.gov. Submit comments
  via the Federal eRulemaking portal by
  searching the OMB control number
  9000–0054. Select the link "Comment
  Now" that corresponds with
  "Information Collection "Information
  Collection 9000–0054, U.S. Flag Air
  Carriers Statement". Follow the
  instructions provided on the screen.
  Please include your name, company
  name (if any), and "Information
  Collection 9000–0054, U.S. Flag Air
  Carriers Statement" on your attached
  document.
- Mail: General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms.

Flowers/IC 9000–0054, U.S. Flag Air Carriers Statement.

Instructions: Please submit comments only and cite Information Collection 9000–0054, U.S. Flag Air Carriers Statement, in all correspondence related to this collection. All comments received will be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a>, including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr. Procurement Analyst, Contract Policy Division, GSA 202–501–1448 or via email at curtis.glover@gsa.gov.

#### SUPPLEMENTARY INFORMATION:

#### A. Purpose

Section 5 of the International Air Transportation Fair Competitive Practices Act of 1974 (49 U.S.C. 1517) (Fly America Act) requires that all Federal agencies and Government contractors and subcontractors at FAR 47.402, use U.S.-flag air carriers for U.S. Government-financed international air transportation of personnel (and their personal effects) or property, to the extent that service by those carriers is available. It requires the Comptroller General of the United States, in the absence of satisfactory proof of the necessity for foreign-flag air transportation, to disallow expenditures from funds, appropriated or otherwise established for the account of the United States, for international air transportation secured aboard a foreignflag air carrier if a U.S.-flag air carrier is available to provide such services. In the event that the contractor selects a carrier other than a U.S.-flag air carrier for international air transportation during performance of the contract, the contractor shall include per FAR clause 52.247-64 a statement on vouchers involving such transportation. The contracting officer uses the information furnished in the statement to determine whether adequate justification exists for the contractor's use of other than a U.S.flag air carrier.

#### **B.** Annual Reporting Burden

Respondents: 150. Responses per Respondent: 2. Annual Responses: 300. Hours per Response: .25. Total Burden Hours: 75.

#### C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the FAR, and whether it will have practical utility; whether our estimate of the public burden of this collection of

information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals:
Requesters may obtain a copy of the information collection documents from the General Services Administration,
Regulatory Secretariat Division (MVCB),
1800 F Street NW., Washington, DC
20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0054,
Submission for OMB Review; U.S.-Flag
Air Carriers Statement, in all correspondence.

Dated: July 15, 2015.

#### Edward Loeb.

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2015–17762 Filed 7–17–15; 8:45 am]

BILLING CODE 6820-EP-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

#### Multi-Agency Informational Meeting Concerning Compliance With the Federal Select Agent Program; Public Webcast

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice of public webcast.

**SUMMARY:** The HHS Centers for Disease Control and Prevention's Division of Select Agents and Toxins (DSAT) and the USDA Animal and Plant Health Inspection Service (APHIS), Agriculture Select Agent Services (AgSAS) are jointly charged with the oversight of the possession, use and transfer of biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products (select agents and toxins). This joint effort constitutes the Federal Select Agent Program. The purpose of the webcast is to provide guidance related to the Federal Select Agent Program for interested individuals.

**DATES:** The webcast will be held on Thursday, November 19, 2015 from 12 p.m. to 4 p.m. EST. All who wish to join the webcast must register by October 23,

2015. Registration instructions can be found on the Web site http://www.selectagents.gov.

ADDRESSES: The webcast will be broadcast from the Centers for Disease Control and Prevention's facility, 1600 Clifton Road, Atlanta, GA 30333. This will only be produced as a webcast, therefore no accommodations will be provided for in-person participation.

FOR FURTHER INFORMATION CONTACT: CDC: Ms. Diane Martin, Division of Select Agents and Toxins, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS A–46, Atlanta, GA 30329; phone: 404–718–2000; email: lrsat@cdc.gov.

APHIS: Dr. Keith Wiggins, APHIS Agriculture Select Agent Services, 4700 River Road, Unit 2, Riverdale, MD 20737; phone: 301–851–3300 (option 3); email: AgSAS@aphis.usda.gov.

**SUPPLEMENTARY INFORMATION:** The public webcast is an opportunity for the affected community (*i.e.*, registered entity responsible officials, alternate responsible officials, and entity owners) and other interested individuals to obtain specific regulatory guidance and information concerning biosafety, security and incident response issues related to the Federal Select Agent Program.

Representatives from the Federal Select Agent Program will be present during the webcast to address questions and concerns from the Web participants.

Individuals who want to participate in the webcast must complete their registration online by October 23, 2015. The registration instructions are located on this Web site: http://www.selectagents.gov.

Dated: July 15, 2015.

#### Pamela J. Cox,

Director, Division of the Executive Secretariat, Centers for Disease Control and Prevention. IFR Doc. 2015–17734 Filed 7–17–15: 8:45 aml

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

## Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention—Health Disparities Subcommittee (HDS)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned subcommittee: Times And Dates: 1:00 p.m.–2:30 p.m., EDT, August 11, 2015

Place: This meeting will be held by teleconference. To participate in the teleconference, please dial (866) 763–0273 Passcode: 6158968.

Status: This meeting is open to the public, limited only by the availability of telephone ports. The public is welcome to participate during the public comment period, which is tentatively scheduled from 2:15 to 2:30 p.m.

Purpose: The Subcommittee will provide advice to the CDC Director through the ACD on strategic and other health disparities and health equity issues and provide guidance on opportunities for CDC.

Matters For Discussion: The Health Disparities Subcommittee members will discuss progress toward implementation of the Health Disparities Subcommittee recommendations and discuss the intersection of health disparities and women's health.

The agenda is subject to change as priorities dictate.

Contact Person For More Information: Leandris Liburd, Ph.D., M.P.H., M.A., Designated Federal Officer, Health Disparities Subcommittee, Advisory Committee to the Director, CDC, 1600 Clifton Road, NE., M/S K-77, Atlanta, Georgia 30333 Telephone (770) 488– 8343, Email: LEL1@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

#### Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015–17661 Filed 7–17–15; 8:45 am] BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

[60Day-15-15AUJ; Docket No. CDC-2015-0056]

## Proposed Data Collection Submitted for Public Comment and Recommendations

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the Paul Coverdell National Acute Stroke Program (PCNASP) reporting system, which was established to improve quality of care for acute stroke patients from onset of signs and symptoms through hospital care and rehabilitation and recovery. DATES: Written comments must be received on or before September 18, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0056 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS– D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

**Please note:** All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

# FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600

Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new

proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

#### **Proposed Project**

Paul Coverdell National Acute Stroke Program (PCNASP)—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Stroke is the fifth leading cause of death in the United States and results in approximately 130,000 deaths per year. Additionally, approximately 800,000 stroke events are reported each year, including approximately 250,000

recurrent strokes. However, many strokes are preventable, or their severity can be reduced through coordinated care that is delivered in a timely manner.

Stroke outcomes depend upon the rapid recognition of signs and symptoms of stroke, prompt transport to a treatment facility, and early rehabilitation. Improving outcomes requires a coordinated systems approach involving pre-hospital care, emergency department and hospital care, rehabilitation, prevention of complications, and ongoing secondary prevention. Each care setting has unique opportunities for improving the quality of care provided and access to available professional and clinical care at the local level within a coordinated statebased system of care.

Through the Paul Coverdell National Acute Stroke Program (PCNASP), CDC has been continuously working to measure and improve acute stroke care using well-known quality improvement strategies coupled with frequent evaluation of results. PCNASP awardees are state health departments who work with participating hospitals and EMS agencies in their jurisdictions to improve quality of care for stroke patients. State-based efforts include identifying effective stroke treatment centers and building capacity and infrastructure to ensure that stroke patients are routed to effective treatment centers in a timely manner.

During initial cooperative agreement cycles, PCNASP awardees focused on in-hospital quality of care (QoC) issues with technical assistance provided by CDC. Through lessons learned during this process and other supporting evidence in the field, it has become evident that it is also important to examine pre- and post-hospital transitions of care to link the entire continuum of stroke care when improving QoC for stroke patients.

The PCNASP will continue under a new five-year cooperative agreement, subject to available funding, to begin on or around July 1, 2015. The new funding period reflects additional emphasis on pre-hospital quality of care as well as the post-hospital transition of care setting from hospital to home and the next care provider. Therefore, awardees will systematically collect and report data on hospital capacity and all three phases of the stroke care continuum.

The new cooperative agreement funding cycle will include pre-hospital (EMS), in-hospital, and post-hospital patient care data. Data to be collected for pre- and in-hospital care closely align with standards of The Joint Commission (TJC), the American Heart Association's Get With The Guidelines (GWTG) program, and the National **Emergency Medical Services** Information System (NEMSIS). CDC and awardees will work on defining performance measures for the posthospital transition of care setting. Data from these three settings will be transmitted from the awardees to CDC quarterly. The average burden per response for this data will vary between 30-90 minutes. The burden will be 30 minutes each for independent submission of information relating to the pre-hospital, in-hospital, and posthospital phases of patient care. Alternatively, the burden will be 90 minutes for awardees who transmit pre-, in-, and post-hospital data as one combined file. CDC accepts file transmissions as individual phases or combined.

In addition, the new cooperative agreement funding cycle will also include primary data collection of hospital inventory data to understand the capacity and infrastructure of the hospitals that admit and treat stroke patients. Each hospital will report inventory information to its PCNASP awardee annually. The average burden per response is 15 minutes. In addition, each PCNASP awardee will prepare an annual aggregate hospital inventory file for transmission to CDC. The average burden of reporting hospital inventory information for each PCNASP awardee is 8 hours per response. All patient, hospital, and EMS provider data that is submitted to CDC by PCNASP awardees will be de-identified and occur through secure data systems.

Proposed data elements and quality indicators may be updated over time to include new or revised items based on evolving recommendations and standards in the field to improve the quality of stroke care.

OMB approval is requested for three years. All information is submitted to CDC electronically. Participation is voluntary and there are no costs to respondents other than their time.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
PCNASP Awardee	Hospital Inventory	9 9 9	1 4 4 4	8 30/60 30/60 30/60	72 18 18 18
Hospital	Hospital Inventory	400	1	15/60	100
Total					226

#### Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention

[FR Doc. 2015–17699 Filed 7–17–15; 8:45 am] BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

Informational Meeting: The Importation and Exportation of Infectious Biological Agents, Infectious Substances and Vectors; Public Webcast

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). **ACTION:** Notice of public webcast.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS) is hosting a public webcast which will include representatives from the U.S. Department of Transportation, USDA Animal and Plant Health Inspection Services, CDC Division of Global Migration and Quarantine, U.S. Customs and Border Protection, U.S. Department of Commerce, U.S. Food and Drug Administration, HHS/Office of the Assistant Secretary for Preparedness and Response/Biomedical Advanced Research and Development Authority. This public webcast will address import and export regulations for infectious biological agents, infectious substances, and vectors, and import and export exemptions. The purpose of this notice is to inform all interested parties, including those individuals and entities already possessing an import or export permit (or license) of the webcast. **DATES:** The webcast will be held on September 16, 2015 from 11 a.m. to 4 p.m. EDT. Registration instructions are

found on the HHS/CDC's Import Permit Program Web site, http://www.cdc.gov/ od/eaipp/importApplication/ agents.htm.

ADDRESSES: The webcast will be broadcast from the Centers for Disease Control and Prevention, 1600 Clifton Road NE., Atlanta, Georgia 30329.

FOR FURTHER INFORMATION CONTACT: Von McClee, Division of Select Agents and Toxins, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS A–46, Atlanta, GA 30333; phone: 404–718–2000; email: lrsat@cdc.gov.

SUPPLEMENTARY INFORMATION: This webcast is an opportunity for the regulated community (i.e., academic institutions and biomedical centers, commercial manufacturing facilities, federal, state, and local laboratories, including clinical and diagnostic laboratories, research facilities, exhibition facilities, and educational facilities) and other interested individuals to obtain specific regulatory guidance and information regarding import and export regulations. The webcast will also provide assistance to those interested in applying for an import or export permit (or license) from federal agencies within the United States.

Instructions for registration are found on the HHS/CDC's Import Permit Program Web site, http://www.cdc.gov/od/eaipp/importApplication/agents.htm. Participants must register by September 2, 2015. This is a webcast only event and there will be no on-site participation at the HHS/CDC broadcast facility.

Dated: July 15, 2015.

#### Pamela J. Cox,

Director, Division of the Executive Secretariat, Centers for Disease Control and Prevention. [FR Doc. 2015–17735 Filed 7–17–15; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health (ABRWH or Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

Correction: This notice was published in the **Federal Register** on June 30, 2015, Volume 80, Number 125, Pages 37263–37264. The time and date should read as follows:

Time and Date: 8:15 a.m.–5:30 p.m., Mountain Time, July 23, 2015.

Public Comment Time and Date: 5:30 p.m.–6:30 p.m., Mountain Time, July 23, 2015.

Contact Person for More Information: Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road NE., MS E–20, Atlanta, Georgia 30333, telephone: (513) 533–6800, toll free: 1–800–CDC–INFO, email: dcas@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

#### Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2015-17704 Filed 7-17-15; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Administration for Children and Families

## Proposed Information Collection Activity; Comment Request

Title: Accomplishments of the Domestic Violence Hotline, Online Connections and Text (ADVHOCaT) Study.

OMB No.: New Collection.

Description: The National Domestic Violence Hotline (NDVH) and the National Dating Abuse Helpline or Love Is Respect (NDAH/LIR), which are supported by the Division of Family Violence Prevention and Services within the Family and Youth Services Bureau of the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), serve as partners in the intervention, prevention, and resource assistance efforts of the network of family violence, domestic violence, and dating violence service providers.

In order to describe the activities and accomplishments of the NDVH and NDAH/LIR and develop potential new or revised performance measures, the Office of Planning, Research and Evaluation (OPRE), within ACF/HHS is proposing data collection activity as part of the Accomplishments of the Domestic Violence Hotline, Online Connections and Text (ADVHOCaT) Study.

This study will primarily analyze data previously collected by the NDVH and NDAH/LIR as part of their ongoing program activities and monitoring. ACF proposes to collect additional information, including information about the preferred mode (phone, chat, text), ease of use, and perceived safety of each mode of contact.

This data is to be collected through voluntary web-based surveys that are to be completed by those who access the NDVH and NDAH/LIR Web sites. This information will be critical to informing future efforts to monitor and improve the performance of domestic violence hotlines and provide hotline services.

Respondents: Individuals who access the NDVH and NDAH/LIR Web sites.

#### **ANNUAL BURDEN ESTIMATES**

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
NDVH/LIR Preference of Use Survey	5000	1	0.041 hours (150 seconds)	205

Estimated Total Annual Burden Hours: 205 hours.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@ acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to

comments and suggestions submitted within 60 days of this publication.

#### Karl Koerper,

Reports Clearance Officer. [FR Doc. 2015–17687 Filed 7–17–15; 8:45 am] BILLING CODE 4184–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-2406]

Agency Information Collection Activities; Proposed Collection; Comment Request; Market Claims in Direct-to-Consumer Prescription Drug Print Ads

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled, "Market Claims in Direct-to-Consumer Prescription Drug Print Ads." This study will examine the

impact of market claim information in direct-to-consumer (DTC) print advertising for prescription drugs.

**DATES:** Submit either electronic or written comments on the collection of information by September 18, 2015.

ADDRESSES: Submit electronic comments on the collection of information to http://
www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal

Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### Market Claims in Direct-to-Consumer Prescription Drug Print Ads—OMB Control Number 0910—NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The marketing literature divides product attributes ("cues") into intrinsic and extrinsic. Intrinsic cues are physical characteristics of the product (e.g., size,

shape), whereas extrinsic cues are product-related but not part of the product (e.g., price and brand name) (Refs. 1, 2). Research has found that both intrinsic and extrinsic cues can influence perceptions of product quality (Ref. 3). Consumers may rely on product cues in the absence of explicit quality information. The objective quality of prescription drugs is not easily obtained from promotional claims in DTC ads; thus consumers may rely upon extrinsic cues to inform their decisions. Market claims such as "#1 prescribed" and "new" may act as extrinsic cues about the product's quality, independent of the product's intrinsic characteristics. Prior research has found that market leadership claims can affect consumer beliefs about product efficacy, as well as their beliefs about doctors' judgments about product efficacy (Ref. 4). One limitation of these prior studies is the lack of quantitative information about product efficacy in the information provided to respondents. Research indicates that providing consumers with efficacy information generally improves understanding and facilitates decisionmaking (Refs. 5, 6). Efficacy information may moderate the effect of the extrinsic cue by providing insight into characteristics that would otherwise be unknown. Other research has shown that consumers are able to use information about efficacy to inform judgments about the product (Refs. 6, 7).

The Office of Prescription Drug Promotion plans to investigate, through empirical research, the impact of market claims on prescription drug product perceptions with and without quantitative information about product efficacy. This will be investigated in DTC print advertising for prescription drugs.

The project consists of two parts; a main study and a followup study. Pretesting will be conducted to assess and identify problems with the questionnaire, stimuli, and procedures. Participants will be consumers who selfidentify as having been diagnosed with diabetes. All participants will be 18 years of age or older. We will exclude individuals from the consumer sample who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Recruitment and administration of the study will take place over the Internet. Participation is estimated to take no more than 30 minutes.

In the main study, participants will be randomly assigned to view one of nine possible versions of an ad, as depicted in table 1. The two variables of interest are type of market claim (#1 Prescribed, New) and level of efficacy information (high, low, or none). Efficacy information will be operationalized in the form of simple quantitative information (for example, product X can provide 50 percent relief for up to 60 percent of patients). We will investigate memory, perception, and understanding of product risks and benefits; perception and understanding of the market claim; perception of product quality; perceptions of product acceptance by doctor, intention to seek more information about the product; and perceptions of trust/skepticism regarding product claims and the sponsor. To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described below, we will have sufficient power to detect small- to medium-sized effects in the main study.

TABLE 1—MAIN STUDY DESIGN TYPE OF MARKET CLAIM

	#1 Prescribed	New	None (control)
Efficacy Level Information:			
High	Α Α	В	C
Low	D	E	F
None (control)	G	Н	I

The followup study will examine the tradeoff between efficacy level and market share claim using decision analysis techniques. Participants will be asked to choose between two different

DTC print ads over 48 trials. One set of DTC ads will feature the two claims from the main study. The other set of DTC ads will depict 48 different levels of product efficacy. Participants will be

asked to choose one product on one or more dependent measures.

FDA estimates the burden of this collection of information as follows:

#### TABLE 2—ESTIMATED BURDEN 1

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Sample outgo (pretests and main survey)	16,384				
Screener completes	1,638	1	1,638	.03 (2 minutes)	49
Eligible	1,556				
Completes, Pretest 1	252	1	252	.5 (30 minutes)	126
Completes, Pretest 2	252	1	252	.5 (30 minutes)	126
Completes, Main Study	495	1	495	.5 (30 minutes)	248
Completes, Pretest 3	108	1	108	.25 (15 minutes)	27
Completes, Followup Study	216	1	216	.25 (15 minutes)	54
Total					630

<sup>&</sup>lt;sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

#### References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <a href="http://www.regulations.gov">http://www.regulations.gov</a>.

- Lee, M. and Y.C. Lou, "Consumer Reliance on Intrinsic and Extrinsic Cues in Product Evaluations: A Conjoint Approach," *Journal of Applied Business Research*, 12(1), pp. 21–29 (2011).
- Teas, R.K. and S. Agarwal, "The Effects of Extrinsic Product Cues on Consumers" Perceptions of Quality, Sacrifice, and Value," Journal of the Academy of Marketing Science, 28(2), pp. 278–290 (2000).
- Rao, A.R. and K.B. Monroe, "The Effect of Price, Brand Name, and Store Name on Buyers' Perceptions of Product Quality: An Integrative Review," Journal of Marketing Research, pp. 351–357 (1989).
- Mitra, A., J.L. Swasy, and K.J. Aikin, "How Do Consumers Interpret Market Leadership Claims in Direct-to-Consumer Advertising of Prescription Drugs?" Advances in Consumer Research, 33, pp. 381–387 (2006).
- O'Donoghue, A., H.K. Sullivan, D. Aikin, R. Chowdhury, et al., "Presenting Efficacy Information in Direct to Consumer Prescription Drug Advertisements," Patient Education Counsel, 95(2), pp. 271–80 (2014).
- Schwartz, L.M., S. Woloshin, and H.G. Welch, "Using a Drug Facts Box to Communicate Drug Benefits and Harmstwo Randomized Trials," Annals of Internal Medicine, 150(8), pp. 516–527 (2009).
- Sullivan, H.W., A. C. O'Donoghue, and K.J. Aikin, "Presenting Quantitative Information About Placebo Rates to Patients," *JAMA Internal Medicine*, doi: 10.1001/jamainternmed.2013.10399 (2013).

Dated: July 15, 2015.

#### Leslie Kux,

Associate Commissioner for Policy.
[FR Doc. 2015–17725 Filed 7–17–15; 8:45 am]
BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. FDA-2010-N-0128]

Prescription Drug User Fee Act; Stakeholder Consultation Meetings on the Prescription Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intention To Participate

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for notification of participation.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders-including patient and consumer advocacy groups, health care professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Prescription Drug User Fee Act (PDUFA). The statutory authority for PDUFA expires in September 2017. At that time, new legislation will be required for FDA to continue collecting user fees for the prescription drug program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next PDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

**DATES:** Submit notification of intention to participate in these series of meetings by August 28, 2015. Stakeholder

meetings will be held monthly. It is anticipated that they will commence in September or October 2015.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to *PDUFAReauthorization@fda.hhs.gov.* The meetings will be held at the FDA campus, 10903 New Hampshire Ave., Silver Spring, MD 20993.

#### FOR FURTHER INFORMATION CONTACT:

Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993, 301–796– 5003, FAX: 301–847–8443.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

FDA is requesting that public stakeholders-including patient and consumer advocacy groups, health care professionals, and scientific and academic experts—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of PDUFA. PDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of human drugs. The authorization for the current program (PDUFA V) expires in September 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human drug review process.

Section 736B(d) of the FD&C Act (21 U.S.C. 379h–2(d)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer groups, health care professionals, and scientific and academic experts, in developing recommendations for the next PDUFA program. FDA will initiate the reauthorization process by holding a public meeting on July 15, 2015, where stakeholders and other members of the public will be given an opportunity to

present their views on the reauthorization. The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence in September or October 2015.

FDA is issuing this Federal Register notice to request that stakeholder representatives from patient and consumer groups, health care professional associations, as well as scientific and academic experts, notify FDA of their intent to participate in the periodic stakeholder consultation meetings on PDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice will be included in all stakeholder consultation discussions while FDA negotiates with the regulated industry. If a stakeholder decides to participate in these monthly meetings at a later time, that stakeholder may join the remaining monthly stakeholder consultation meetings after notifying FDA of this intention (see ADDRESSES). These stakeholder discussions will satisfy the consultation requirement in section 736B(d)(3) of the FD&C Act.

## II. Notification of Intent To Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding PDUFA reauthorization, please provide notification by email to PDUFAReauthorization@fda.hhs.gov by August 28, 2015. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification.

Dated: July 14, 2015.

#### Leslie Kux,

Associate Commissioner for Policy. [FR Doc. 2015–17684 Filed 7–17–15; 8:45 am] BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **Food and Drug Administration**

[Docket No. FDA-1992-N-0199]

## David J. Brancato: Grant of Special Termination; Final Order Terminating Debarment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) granting special termination of the debarment of David J. Brancato. FDA bases this order on a finding that Dr. Brancato provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction, and that special termination of Dr. Brancato's debarment serves the interest of justice and does not threaten the integrity of the drug approval process.

**DATES:** This order is effective July 20, 2015.

ADDRESSES: Comments should reference Docket No. FDA-1992-N-0199 and be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr. (ELEM–4144), Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION: In a Federal Register notice dated January 6, 1994 (59 FR 00751), David J. Brancato, a former review chemist with FDA's Division of Generic Drugs was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 306(a) of the FD&C Act (21 U.S.C. 335a(a)). The debarment was based on FDA's finding that Dr. Brancato was convicted of a felony under Federal law for conduct relating to the development, or approval of any drug product, or otherwise relating to the regulation of a drug product. On May 26, 1998, Dr. Brancato applied for special termination of debarment, under section 306(d)(4) of the FD&C Act, as amended by the Generic Drug Enforcement Act. On April 15, 2015, the Agency requested additional information. On April 20, 2015, Dr. Brancato provided the requested information.

Under section 306(d)(4)(C) and (d)(4)(D) of the FD&C Act, FDA may limit the period of debarment of a permanently debarred individual if the Agency finds that: (1) The debarred individual has provided substantial assistance in the investigation or prosecution of offenses described in section 306(a) or (b) of the FD&C Act or relating to a matter under FDA's jurisdiction; (2) termination of the debarment serves the interest of justice; and (3) termination of the debarment does not threaten the integrity of the drug approval process.

Special termination of debarment is discretionary with FDA. FDA generally considers a determination by the Department of Justice concerning the substantial assistance of a debarred individual conclusive in most cases. Dr. Brancato cooperated with the United States Attorney's Office in the investigation of several individuals, as substantiated by letters submitted to the Agency by Thomas Holland, a Special Agent in the Office of the Inspector General, U.S. Department of Health and Human Services, and the U.S. Attorney's Office for the District of Columbia. His cooperation contributed to the successful prosecution of these individuals, and in one instance continued over a period of 7 years. Accordingly, FDA finds that Dr. Brancato provided substantial assistance as required by section 306(d)(4)(C) of the FD&C Act.

The additional requisite showings, *i.e.*, that termination of debarment serves the interest of justice and poses no threat to the integrity of the drug approval process, are difficult standards to satisfy. In determining whether these have been met, the Agency weighs the significance of all favorable and unfavorable factors in light of the remedial, public health-related purposes underlying debarment. Termination of debarment will not be granted unless, weighing all favorable and unfavorable information, there is a high level of assurance that the conduct that formed the basis for debarment has not recurred and will not recur, and that the individual will not otherwise pose a threat to the integrity of the drug approval process.

The evidence presented to FDA in support of termination shows that Dr. Brancato was convicted for a first offense; that he has no prior or subsequent convictions for conduct described under the FD&C Act and has committed no other wrongful acts affecting the drug approval process; and that his character and scientific accomplishments are highly regarded by his professional peers. The evidence

presented supports the conclusion that the conduct upon which Dr. Brancato's debarment was based is unlikely to recur. For these reasons, the Agency finds that termination of Dr. Brancato's debarment serves the interest of justice and will not pose a threat to the integrity of the drug approval process.

Under section 306(d)(4)(D) of the FD&C Act, the period of debarment of an individual who qualifies for special termination may be limited to less than permanent but to no less than 1 year. Dr. Brancato's period of debarment, which commenced on January 6, 1994, has lasted more than 1 year. Accordingly, the Director of the Office of Enforcement and Import Operations, under section 306(d)(4) of the FD&C Act and under authority delegated to the Director (Staff Manual Guide 1410.35), finds that David J. Brancato's application for special termination of debarment should be granted, and that the period of debarment should terminate immediately, thereby allowing him to provide services in any capacity to a person with an approved or pending drug product application. The Director of Enforcement and Import Operations further finds that because the Agency is granting Dr. Brancato's application, an informal hearing under section 306(d)(4)(C) of the FD&C Act is unnecessary.

As a result of the foregoing findings, Dr. David J. Brancato's debarment is terminated effective (see **DATES**) (21 U.S.C. 335a(d)(4)(C) and (d)(4)(D)).

Dated: July 15, 2015.

#### Leslie Kux,

Associate Commissioner for Policy.
[FR Doc. 2015–17712 Filed 7–17–15; 8:45 am]
BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. FDA-2015-N-1196]

List of Bulk Drug Substances That May Be Used by an Outsourcing Facility To Compound Drugs for Use in Animals; Extension of Nomination Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of nomination period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the nomination period for the notice that appeared in the **Federal Register** of May 19, 2015. In the notice, FDA requested nominations for a list of bulk drug

substances that may be used by facilities registered as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to compound animal drugs from bulk substances, in accordance with FDA's draft guidance for industry (GIF) #230, "Compounding Animal Drugs from Bulk Drug Substances." The FDA is taking this action in response to a request for an extension to allow interested persons additional time to submit nominations. DATES: Submit either electronic or written nominations for the bulk drug substances list by November 16, 2015. ADDRESSES: You may submit

#### **Electronic Submissions**

methods:

Submit electronic nominations in the following way:

nominations by any of the following

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

#### **Written Submissions**

Submit written nominations in the following ways:

• Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA—2015—N—1196. All nominations received may be posted without change to <a href="http://www.regulations.gov">http://www.regulations.gov</a>, including any personal information provided. For additional information on submitting nominations, see the "Request for Nominations" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or nominations received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine, Food and Drug Administration (HFV–210), 7519 Standish Pl., Rockville, MD 20855, 240–402–5745, neal.bataller@fda.hhs.gov.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

In the **Federal Register** of May 19, 2015 (80 FR 28622), FDA published a notice with a 90-day nomination period for the list of bulk drug substances that

may be used by a facility registered as an outsourcing facility under section 503B of the FD&C Act (21 U.S.C. 353B) to compound drugs for use in animals in accordance with FDA's draft GFI #230, "Compounding Animal Drugs from Bulk Drug Substances." That notice describes the information that should be provided to the FDA in support of each nomination.

FDA has received a request for a 90-day extension of the nomination period as the requestor wanted more time to nominate drugs to the list and to provide supporting data. FDA has considered the request and is extending the nomination period for 90 days, until November 16, 2015. The FDA believes that a 90-day extension allows adequate time for interested persons to submit nominations without significantly delaying consideration of these nominations.

#### **II. Nomination Process**

The process for nominations for bulk drug substances that may be used by facilities registered as outsourcing facilities under section 503B of the FD&C Act to compound animal drugs from bulk drug substances is described in the previous notice published May 19, 2015. FDA cannot guarantee that all drugs nominated during the nomination period will be considered for initial inclusion in Appendix A at the time of its initial publication. Nominations submitted during the nomination period (ending on November 16, 2015) that are not evaluated and included in Appendix A at the time of its initial publication will receive consideration for later addition to Appendix A. In addition, individuals and organizations may petition FDA, in accordance with 21 CFR 10.30, to make additional amendments to Appendix A after the nomination period.

#### III. Request for Nominations

Interested persons may submit either electronic nominations to <a href="http://www.regulations.gov">http://www.regulations.gov</a> or written nominations to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of nominations. Identify nominations with the docket number found in brackets in the heading of this document. Received nominations may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <a href="http://www.regulations.gov">http://www.regulations.gov</a>.

Dated: July 15, 2015.

#### Leslie Kux.

Associate Commissioner for Policy.
[FR Doc. 2015–17729 Filed 7–17–15; 8:45 am]
BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **Food and Drug Administration**

[Docket No. FDA-2015-N-2412]

Determination That TESSALON (Benzonatate) Capsules and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration,

HHS.

**ACTION:** Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

#### FOR FURTHER INFORMATION CONTACT:

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6207, Silver Spring, MD 20993–0002, 301–796–8363.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDAs applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products with Therapeutic Equivalence Evaluations,"

which is generally known as the "Orange Book." Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed. (As requested by the applicant, FDA withdrew approval of NDA 050448 for GRIFULVIN (griseofulvin) Oral Suspension in the **Federal Register** of August 16, 2001 (66 FR 43017)).

porate Blvd., Bridgewater, NJ 08807.

Application No.	Drug	Applicant
NDA 011210 NDA 012093	TESSALON (benzonatate) Capsule; Oral 200 milligrams (mg) ISORDIL (isosorbide dinitrate) Tablet; Oral 10 mg, 20 mg, 30 mg.	Pfizer Inc., 1 Giralda Farms, Madison, NJ 07940.  Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 018702	ACLOVATE (alclometasone dipropionate) Ointment; Topical 0.05%.	Fougera Pharmaceuticals Inc., 60 Baylis Rd., P.O. Box 2006, Melville, NY 11747.
NDA 018707	ACLOVATE (alclometasone dipropionate) Cream; Topical 0.05%.	Do.
NDA 018936	SARAFEM (fluoxetine hydrochloride (HCl)) Capsule; Oral Equivalent to (EQ) 10 mg Base, EQ 20 mg Base.	Eli Lilly and Co., Lilly Corp. Ctr., Indianapolis, IN 46285.
NDA 018988	VASOCIDIN (prednisolone sodium phosphate; sulfacetamide sodium), Solution/Drops; Ophthalmic, EQ 0.23% phosphate; 10%.	Novartis Pharmaceuticals Corp., 105 Eisenhower Pky., 280 Corporate Center, Roseland, NJ 07068.
NDA 019898	PRAVACHOL (pravastatin sodium) Tablet; Oral 10 mg	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543-4000.
NDA 020092	DILACOR XR (diltiazem HCl) Capsule, Extended-Release; Oral 120 mg, 180 mg, 240 mg.	Actavis Laboratories UT, Inc., 577 Chipeta Way, Salt Lake City, UT 84108.
NDA 021551	HALFLYTELY (polyethylene glycol 3350; potassium chloride; sodium bicarbonate; sodium chloride) For Solution and bisacodyl Delayed-Release Tablets); Oral 210 grams (g); 0.74 g; 2.86 g; 5.6 g; 5 mg.	Braintree Laboratories, Inc., 60 Columbia St., P.O. Box 850929, Braintree, MA 02185.
NDA 021871	LOESTRIN 24 FE (ethinyl estradiol; norethindrone acetate) Tablet; Oral 0.02 mg; 1 mg.	Warner Chilcott Co. LLC, Union Street Rd. 195 KM 1.1., Fajardo, Puerto Rico 00738.
NDA 050448	GRIFULVIN V (griseofulvin, microcrystalline) Suspension; Oral 125 mg/5 milliliters (mL).	Johnson & Johnson Consumer Products Co., 199 Grandview Rd., Skillman, NJ 08558.
NDA 050719	HELIDAC (bismuth subsalicylate; metronidazole; tetracycline HCl) Tablet, Chewable, Tablet, Capsule; Oral 262.4 mg; 250 mg, 500 mg.	Prometheus Laboratories Inc., 9410 Carroll Park Dr., San Diego, CA 92121.
ANDA 040454	PROMETHAZINE HYDROCHLORIDE (promethazine HCI) Injectable; Injection 25 mg/mL, 50 mg/mL.	Teva Pharmaceuticals USA, 425 Privet Rd., Horsham, PA 19044.
ANDA 062483	GRIFULVIN V (griseofulvin, microsize) Suspension; Oral 125 mg/5 mL.	Valeant Pharmaceuticals Luxembourg S.a.r.l, C/O Valeant Pharmaceuticals North America LLC, 400 Somerset Cor-

Application No.	Drug	Applicant
ANDA 088762	PROMETH W/DEXTROMETHORPHAN (dextromethorphan hydrobromide; promethazine HCl) Syrup; Oral 15 mg/5 mL; 6.25 mg/5 mL.	

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 15, 2015.

#### Leslie Kux,

Associate Commissioner for Policy. [FR Doc. 2015–17730 Filed 7–17–15; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Bioequivalence Recommendations for Lubiprostone; Revised Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration,

**ACTION:** Notice.

SUMMARY: The Food and Drug
Administration (FDA) is announcing the
availability of a revised draft guidance
for industry on lubiprostone capsules
entitled "Bioequivalence
Recommendations for Lubiprostone."
The recommendations provide specific
guidance on the design of
bioequivalence (BE) studies to support
abbreviated new drug applications
(ANDAs) for lubiprostone capsules.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 18, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993—0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

In the Federal Register of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry, "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at http://www.fda.gov/Drugs/ GuidanceComplianceRegulatory Information/Guidances/default.htm. As described in that guidance, FDA adopted this process as a means to develop and disseminate productspecific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for lubiprostone capsules.

FDA initially approved new drug application (NDA) 021908 for AMITIZA

capsules in January 2006. There are no approved ANDAs for this product. In August 2010, we issued a draft guidance for industry on BE recommendations for generic lubiprostone capsules. We are now issuing a revised draft guidance for industry on BE recommendations for generic lubiprostone capsules ("Bioequivalence Recommendations for Lubiprostone").

In January 2014, Sucampo Pharma Americas, LLC, manufacturer of the reference listed drug, AMITIZA, submitted a citizen petition requesting that FDA revise the BE requirements for any new drug product that references AMITIZA and seeks approval by means of demonstrating BE to AMITIZA. FDA has reviewed the issues raised in the petition and is responding to the petition (Docket No. FDA–2014–P–0144).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for lubiprostone capsules. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

#### II. Comments

Interested persons may submit either electronic comments regarding this document to <a href="http://www.regulations.gov">http://www.regulations.gov</a> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <a href="http://www.regulations.gov">http://www.regulations.gov</a>.

#### III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/Drugs/Guidance ComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: July 15, 2015.

#### Leslie Kux,

Associate Commissioner for Policy. [FR Doc. 2015–17726 Filed 7–17–15; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: HIV/AIDS Innovative Research Applications.

Date: August 4, 2015.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435– 1775, rubertm@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 14, 2015.

#### Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17648 Filed 7–17–15; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **National Institutes of Health**

#### Eunice Kennedy Shriver National Institute of Child Health and Human Development Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: August 31, 2015.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852.

Contact Person: Cathy Wedeen, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6878, wedeenc@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: July 14, 2015.

#### Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17646 Filed 7–17–15; 8:45 am] BILLING CODE 4140–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **National Institutes of Health**

#### Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel.

Date: August 12, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852.

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6680, skandasa@ mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: July 14, 2015.

#### Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17649 Filed 7–17–15; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HOMELAND SECURITY

## Federal Emergency Management Agency

[Docket ID FEMA-2015-0001]

#### **Final Flood Hazard Determinations**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Final Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

**DATES:** The effective date of August 3, 2015 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online

through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) Luis. Rodriguez3@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema. gov/fhm/fmx\_main.html.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at www.msc.fema.gov.

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Date: June 16, 2015.

#### Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
	a, and Incorporated Areas =EMA-B-1412
Unincorporated Areas of Augusta County	Augusta County Community Development Office, 18 Government Center Lane, Verona, VA 24482.
	ginia (All Jurisdictions) FEMA-B-1412
Unincorporated Areas of New Kent County	New Kent County Department of Planning and Community Development, 12007 Courthouse Circle, New Kent, VA 23124.
	ginia (Independent City) =EMA-B-1404
City of Portsmouth	Department of Planning, City Hall Building, 801 Crawford Street, 4th Floor, Portsmouth, VA 23704.
	inia, and Incorporated Areas =EMA–B–1401
Town of Dumfries	Town Hall, Zoning Administrator's Office, 101 South Main Street, Dumfries, VA 22026.  Town Hall, 337 Fifth Avenue, Quantico, VA 22134.  Prince William County Department of Public Works, Watershed Management Branch, 5 County Complex Court, Prince William, VA 22192.
	nia (Independent City) FEMA-B-1401
City of Suffolk	City Hall, Planning and Community Development Office, 442 West Washington Street, Suffolk, VA 23434.

[FR Doc. 2015-17666 Filed 7-17-15; 8:45 am]

BILLING CODE 9110-12-P

## DEPARTMENT OF HOMELAND SECURITY

## Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4223-DR; Docket ID FEMA-2015-0002]

Texas; Amendment No. 3 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4223–DR), dated May 29, 2015, and related determinations.

DATES: Effective date: June 16, 2015.

#### FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Texas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 29, 2015.

Dallas and Nueces Counties for Individual Assistance.

Cooke, Fannin, Grayson, Liberty, and Walker Counties for Individual Assistance (already designated for Public Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance— Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households-Other Needs; 97.036, Disaster Grants—Public Assistance

(Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

#### W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2015-17669 Filed 7-17-15; 8:45 am]

BILLING CODE 9111-23-P

## DEPARTMENT OF HOMELAND SECURITY

#### Federal Emergency Management Agency

[Docket ID FEMA-2015-0001]

#### **Final Flood Hazard Determinations**

**AGENCY:** Federal Emergency Management Agency, DHS. **ACTION:** Final notice.

**SUMMARY:** Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

**DATES:** The effective date of August 17, 2015 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map

Repository address listed in the tables below and will be available online through the FEMA Map Service Center at www.msc.fema.gov by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) Luis.Rodriguez3@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at www.floodmaps.fema.gov/fhm/fmx\_main.html.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at <a href="https://www.msc.fema.gov">www.msc.fema.gov</a>.

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

Date: June 16, 2015.

#### Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Non-watershed-based studies:

Community

Community map repository address

Navajo County, Arizona, and Incorporated Areas
Docket No.: FEMA-B-1347

City of Holbrook 465 1st Avenue, Holbrook, AZ 86025.
City of Show Low 465 1st Avenue, Holbrook, AZ 85901.
Town of Pinetop-Lakeside 465 North Niels Hansen Lane, Lakeside, AZ 85929.

Community map repository address			
County Flood Control District, 100 East Code Talkers Drive, ook, AZ 86025.			
rporated Areas 1292			
I, 210 South 8th Street, Cannelton, IN 47520. g and Zoning, City Hall, 700 Main Street, Tell City, IN 47586. all, 330 Harrison Street, Troy, IN 47588. punty Courthouse, 2219 Payne Street, Tell City, IN 47586.			
ncorporated Areas			
I, 401 East Main Street, Fruitland, MD 21826. I, 125 North Division Street, Salisbury, MD 21801. all, 100 South Pennsylvania Avenue, Delmar, MD 21875. all, 201 Station Street, Mardela Springs, MD 21837. all, 401 Main Street, Sharptown, MD 21861. all, 7360 Main Street, Willards, MD 21874. co County Government Office Building, 125 North Division , Room 201, Salisbury, MD 21801.			
Jurisdictions) 1404			
nk Town Hall, 273 Main Street, Grahamsville, NY 12740.			
Beaver County, Pennsylvania (All Jurisdictions)  Docket No.: FEMA-B-1412			
Hall, 600 11th Street, Ambridge, PA 15603.  Hall, 149 State Street, Baden, PA 15005.  Municipal Building, 469 Third Street, Beaver, PA 15009.  Ver Borough Municipal Building, 114 Forest Drive, Darlington.  115.  ater Borough Municipal Building, 199 Boundary Lane, Bridge.  PA 15009.  Hall, 1208 Third Avenue, Conway, PA 15027.  Hall, 604 Morris Street, Darlington, PA 16115.  Hall, 760 Spruce Avenue, East Rochester, PA 15074.  Borough Office, 510 Second Avenue, Eastvale, Beaver Falls.  1010.  Borough Municipal Building, 2856 Conway Wallrose Road,  PA 15005.  Borough Secretary's Office, 158 Beaver Street, Fallston, PA  15.  Municipal Complex, 901 3rd Avenue, Freedom, PA 15042.  Municipal Complex, 901 3rd Avenue, Freedom, PA 15042.  Borough President's Office, 155 Liberty Avenue, Midland, PA  15.  Borough Office, 102 Second Avenue, Beaver Falls, PA  15.  Building, 262 Main Street, Hookstown, PA 15050.  Poffice, 16208 Midland Beaver Road, Industry, PA 15050.			
n Office, 1620B Midland Beaver Road, Industry, PA 15052. n Office, 3437 3rd Avenue, Koppel, PA 16136. n Office, 936 Midland Avenue, Midland, PA 15059. n Office, 928 Pennsylvania Avenue, Monaca, PA 15061. n Office, 610 3rd Avenue, New Brighton, PA 15066. n Community Hall, 201 Washington Avenue, New Galilee, PA . n Borough Annex Building, 6268 Tuscarawas Road, Industry, 5052. n Heights Borough Hall, 600 7th Avenue, Beaver Falls, PA . n Municipal Building, 350 Adams Street, Rochester, PA 15074. n Building, 164 State Route 3016, Shippingport, PA 15077. n Building, 4069 Jordan Street, South Heights, PA 15081. n ayfield Borough Building, 4609 West 8th Avenue, Beaver Falls, 5010. n 581 Franklin Avenue, Aliquippa, PA 15001. n 715 15th Street, Beaver Falls, PA 15010.			
al I Bayf 501 I, 5			

Community	Community map repository address
Township of Center	Center Township Municipal Building, 224 Center Grange Road, Ali- guippa, PA 15001.
Township of Chippewa	Chippewa Township Municipal Building, 2811 Darlington Road, Beaver Falls, PA 15010.
Township of Darlington	Township Municipal Building, 3590 Darlington Road, Darlington, PA 16115.
Township of Daugherty	Daugherty Township Municipal Building, 2182 Mercer Road, New Brighton, PA 15066.
Township of Franklin Township of Greene	Franklin Township Hall, 897 State Route 288, Fombell, PA 16123. Greene Township Hall, 262 Pittsburgh Grade Road, Hookstown, PA 15050.
Township of Hanover	Hanover Township Hall, 2731 State Route 18, Hookstown, PA 15050. Harmony Township Municipal Building, 2501 Woodland Road, Ambridge, PA 15003.
Township of Hopewell	Hopewell Township Municipal Building, 1700 Clark Boulevard, Aliquippa, PA 15001.
Township of Independence	Independence Township Municipal Building, 104 School Road, Aliquippa, PA 15001.
Township of Marion	Marion Township Municipal Building, 485 Hartzell School Road, Fombell, PA 16123.
Township of New Sewickley	New Sewickley Township Municipal Building, 233 Miller Road, Rochester, PA 15074.
Township of North Sewickley	North Sewickley Township Municipal Building, 893 Mercer Road, Beaver Falls, PA 15010.
Township of Patterson	Patterson Township Municipal Complex, 1600 19th Avenue, Beaver Falls. PA 15010.
Township of Potter	Potter Township Municipal Building, 206 Mowry Road, Monaca, PA 15061.
Township of Pulaski	Pulaski Township Municipal Building, 3401 Sunflower Road, New Brighton, PA 15066.
Township of Raccoon	Raccoon Township Municipal Building, 1234 State Route 18, Aliquippa, PA 15001.
Township of Rochester	Municipal Building, 1013 Elm Street, Rochester, PA 15074.  South Beaver Township Fire Hall, 773 State Route 168, Darlington, PA 16115.
Township of Vanport	Municipal Building, 477 State Avenue, Vanport, PA 15009. White Township Building, 2511 13th Avenue (Clayton Road), Beaver Falls, PA 15010.

#### II. Watershed-based studies:

#### LOWER LITTLE BLUE WATERSHED

Community	Community map repository address	
Jefferson County, Nebraska, and Incorporated Areas Docket No.: FEMA-B-1410		
Village of Daykin Village of Diller Village of Endicott City of Fairbury Village of Harbine Village of Jansen Unincorporated Areas of Jefferson County	Community Center, 503 Commercial Street, Diller, NE 68342. Village Hall, 110 North Scribner Street, Endicott, NE 68350. City Hall, 612 D Street, Fairbury, NE 68352. Harbine Village Hall, 315 Barry Street, Jansen, NE 68377. Village Hall, 57315 715th Road, Jansen, NE 68377.	
Village of Plymouth	Village Hall, 313 East Main Street, Plymouth, NE 68424. Village Hall, 125 Beech Street, Reynolds, NE 68429.	

[FR Doc. 2015–17663 Filed 7–17–15; 8:45 am]

BILLING CODE 9110-12-P

## DEPARTMENT OF HOMELAND SECURITY

## Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4223-DR; Docket ID FEMA-2015-0002]

## Texas; Amendment No. 4 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4223–DR), dated May 29, 2015, and related determinations.

DATES: Effective Date: June 19, 2015.

#### FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the incident period for this disaster is closed effective June 19, 2015.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance— Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households-Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

#### W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2015–17668 Filed 7–17–15; 8:45 am]

BILLING CODE 9111-23-P

## DEPARTMENT OF HOMELAND SECURITY

## Federal Emergency Management Agency

[Docket ID FEMA-2014-0022]

#### **Technical Mapping Advisory Council**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Committee Management; Notice of Federal Advisory Committee Meeting.

**SUMMARY:** The Federal Emergency Management Agency (FEMA) Technical Mapping Advisory Council (TMAC) will meet in person on August 4–5, 2015, in Reston, VA. The meeting will be open to the public.

DATES: The TMAC will meet on Tuesday, August 4, 2015, from 8:00 a.m.–5:30 p.m., and Wednesday, August 5, 2015, from 8:00 a.m.–5:00 p.m., Eastern Daylight Savings Time (EDT). Please note that the meeting will close early if the TMAC has completed its business.

ADDRESSES: The meeting will be held in the auditorium of the United States Geological Survey (USGS) headquarters building located at 12201 Sunrise Valley Drive Reston, VA 20192. Members of the public who wish to attend the meeting must register in advance by sending an email to FEMA-TMAC@fema.dhs.gov (attention Mark Crowell) by 11 p.m. EDT on Thursday, July 30, 2015. Members of the public must check in at the USGS Visitor's entrance security desk; photo identification is required.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in FOR FURTHER INFORMATION CONTACT below as soon as possible.

To facilitate public participation, members of the public are invited to provide written comments on the issues to be considered by the TMAC, as listed in the SUPPLEMENTARY INFORMATION section below. Associated meeting materials will be available at www.fema.gov/TMAC for review by Monday, July 27, 2015. Written comments to be considered by the committee at the time of the meeting must be submitted and received by Wednesday, July 29, 2015, identified by Docket ID FEMA-2014-0022, and submitted by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Email: Address the email TO: FEMA-RULES@fema.dhs.gov and CC: FEMA-TMAC@fema.dhs.gov. Include the docket number in the subject line of the message. Include name and contact detail in the body of the email.
- Mail: Regulatory Affairs Division, Office of Chief Counsel, FEMA, 500 C Street SW., Room 8NE, Washington, DC 20472–3100.

Instructions: All submissions received must include the words "Federal Emergency Management Agency" and the docket number for this action. Comments received will be posted without alteration at http://

www.regulations.gov, including any personal information provided. Docket: For docket access to read background documents or comments received by the TMAC, go to http://www.regulations.gov and search for the Docket ID FEMA—2014—0022.

A public comment period will be held on August 4, 2015, from 4:30 p.m. to 5:00 p.m. and again on August 5, 2015, from 3:30 to 4:00 p.m. Speakers are requested to limit their comments to no more than three minutes. The public comment period will not exceed 30 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact the individual listed below to register as a speaker by close of business on Wednesday, July 29, 2015.

#### FOR FURTHER INFORMATION CONTACT:

Mark Crowell, Designated Federal Officer for the TMAC, FEMA, 1800 South Bell Street Arlington, VA 22202, telephone (202) 646–3432, and email mark.crowell@fema.dhs.gov. The TMAC Web site is: http://www.fema.gov/ TMAC.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix.

As required by the *Biggert-Waters* Flood Insurance Reform Act of 2012, the TMAC makes recommendations to the FEMA Administrator on: (1) How to improve, in a cost-effective manner, the (a) accuracy, general quality, ease of use, and distribution and dissemination of flood insurance rate maps and risk data; and (b) performance metrics and milestones required to effectively and efficiently map flood risk areas in the United States; (2) mapping standards and guidelines for (a) flood insurance rate maps, and (b) data accuracy, data quality, data currency, and data eligibility; (3) how to maintain, on an ongoing basis, flood insurance rate maps and flood risk identification; (4) procedures for delegating mapping activities to State and local mapping partners; and (5) (a) methods for improving interagency and intergovernmental coordination on flood mapping and flood risk determination, and (b) a funding strategy to leverage and coordinate budgets and expenditures across Federal agencies. Furthermore, the TMAC is required to submit an annual report to the FEMA Administrator that contains: (1) A description of the activities of the Council; (2) an evaluation of the status and performance of flood insurance rate maps and mapping activities to revise and update Flood Insurance Rate Maps;

and (3) a summary of recommendations made by the Council to the FEMA Administrator.

The TMAC must also develop recommendations on how to ensure that flood insurance rate maps incorporate the best available climate science to assess flood risks and ensure that FEMA uses the best available methodology to consider the impact of the rise in sea level and future development on flood risk. The TMAC must collect these recommendations and present them to the FEMA Administrator in a future conditions risk assessment and modeling report.

Further, in accordance with the *Homeowner Flood Insurance*Affordability Act of 2014, the TMAC must develop a review report related to flood mapping in support of the National Flood Insurance Program (NFIP).

Agenda: On August 4, 2015, the TMAC members will present and deliberate on draft narrative and recommendations concerning (1) the flood hazard mapping process and product, and (2) future conditions methods and considerations that will be incorporated into both the 2015 Annual Report and the Future Conditions Report. A brief public comment period will take place prior to the end of the meeting.

On August 5, 2015, the TMAC members will continue to deliberate on draft narratives and recommendations concerning (1) the flood hazard mapping process and product, and (2) future conditions methods and considerations that will be incorporated in the two reports. In addition, the TMAC members will identify and coordinate next steps of the TMAC report development. A brief public comment period will take place during the meeting. The full agenda and related briefing materials will be posted for review by July 27, 2015 at http:// www.fema.gov/TMAC.

Dated: July 14, 2015.

#### W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2015-17706 Filed 7-17-15; 8:45 am]

BILLING CODE 9110-12-P

#### **DEPARTMENT OF THE INTERIOR**

#### Fish and Wildlife Service

[FWS-R4-ES-2015-N086; 40120-1112-0000-F2]

#### Receipt of Applications for Endangered Species Permits

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless a Federal permit is issued that allows such activities. The ESA requires that we invite public comment before issuing these permits.

**DATES:** We must receive written data or comments on the applications at the address given below by August 19, 2015.

ADDRESSES: Documents and other information submitted with the applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, GA 30345 (Attn: James Gruhala, Permit Coordinator).

#### FOR FURTHER INFORMATION CONTACT:

James Gruhala, 10(a)(1)(A) Permit Coordinator, telephone 404–679–7097; facsimile 404–679–7081.

**SUPPLEMENTARY INFORMATION:** The public is invited to comment on the following applications for permits to conduct certain activities with endangered and threatened species under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR 17. This notice is provided under section 10(c) of the Act

If you wish to comment, you may submit comments by any one of the following methods. You may mail comments to the Fish and Wildlife Service's Regional Office (see ADDRESSES section) or send them via electronic mail (email) to permitsR4ES@fws.gov. Please include your name and return address in your email message. If you do not receive a confirmation from the Fish and Wildlife Service that we

have received your email message, contact us directly at the telephone number listed above (see FOR FURTHER INFORMATION CONTACT). Finally, you may hand-deliver comments to the Fish and Wildlife Service office listed above (see ADDRESSES).

Before including your address, telephone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comments to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

#### **Permit Applications**

Permit Application Number: TE 13844A–2

Applicant: Anthony Miller, Morgan Worldwide, Lexington, Kentucky.

The applicant requests an amendment of his current permit to add the state of Georgia for permitted activities with the gray bat (*Myotis grisescens*). Permitted activities will continue to be take (enter hibernacula and maternity roost caves, mist-net, harp trap, band, radio-tag, light-tag, wing punch, and salvage) for the purpose of carrying out presence/ absence surveys.

Permit Application Number: TE 12399A-3

Applicant: Ronald Forman, Audubon Nature Institute, New Orleans, Louisiana.

The applicant requests renewal of his current permit to take (rehabilitate, mark, transport, release, and euthanize) Kemp's ridley (Lepidochelys kempii), hawksbill (Eretmochelys imbricata), leatherback (Dermochelys coriacea), green (Chelonia mydas), loggerhead (Caretta caretta), and olive ridley (Lepidochelys olivacea) sea turtles and amendment to authorize the attachment of satellite tags to turtles prior to release, for purposes of veterinary treatment and monitoring of movements and survival of released turtles in the state of Louisiana and elsewhere as directed by the U.S Fish and Wildlife Service.

Permit Application Number: TE 66445B-0

Applicant: Angelina Fowler, Nashville, Tennessee.

The applicant requests a permit to take (capture, identify, release)
Nashville crayfish (*Orconectes shoupi*) and thirteen species of fish for the purpose of conducting presence/absence

surveys in Tennessee, Alabama, Kentucky, and Georgia.

Permit Application Number: TE 66480B–0

Applicant: Thomas Gilbert, Greenwood, Arkansas.

The applicant requests a permit to take (live-trap and release) American burying beetles (*Nicrophorus americanus*) for the purpose of conducting presence/absence surveys in Arkansas and Oklahoma.

Permit Application Number: TE 017853–3

Applicant: Lynne Byrd, Mote Marine Laboratory, Sarasota, Florida.

The applicant requests renewal of his current permit to take (euthanize)
Kemp's ridley (Lepidochelys kempii),
hawksbill (Eretmochelys imbricata),
leatherback (Dermochelys coriacea),
green (Chelonia mydas), loggerhead
(Caretta caretta), sea turtles for the
purpose of veterinary treatment in the
state of Florida and elsewhere as
directed by the U.S Fish and Wildlife
Service.

Permit Application Number: TE 68616B-0

Applicant: Carla Atkinson, University of Alabama, Tuscaloosa, Alabama.

The applicant requests a permit to take (capture, identify, release) 33 species of mussels for the purpose of conducting presence absence surveys in Alabama, Georgia, and Tennessee.

Permit Application Number: TE 121059–2

Applicant: Peggy Measel, Round Mountain Biological & Environmental Studies Inc., Nicholasville, Kentucky.

The applicant requests an amendment of her current permit to add the states of Indiana, Illinois, Virginia, and West Virginia for already permitted activities with Indiana (Myotis sodalis) and gray (Myotis grisescen) bats. Permitted activities will continue to be take (enter hibernacula and maternity roost caves, salvage bead bats, collect hair samples, mist-net, harp trap, band, radio-tag, light-tag, wing punch, and salvage) for the purpose of carrying out presence/absence surveys.

Permit Application Number: TE 64232B–0

Applicant: Joshua R. Young, Lexington, Kentucky.

The applicant requests a permit to take (capture, identify, tag, and release) Virginia big-eared (Corynorhinus (=plecotus) townsendii virginianus), Indiana (Myotis sodalis), gray (Myotis

grisescens), and northern long-eared bats (Myotis septentrionalis) in Alabama, Arkansas, Georgia, Illinois, Indiana, Kentucky, Maryland, Mississippi, Missouri, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Virginia, and West Virginia, and take (capture, identify, release, and collect relict shells) 26 species of freshwater mussels in Kentucky for the purpose of conducting presence/absence surveys.

Dated: June 23, 2015.

#### Leopoldo Miranda,

Assistant Regional Director—Ecological Services, Southeast Region.

[FR Doc. 2015–17070 Filed 7–17–15; 8:45 am]

BILLING CODE 4310-55-P

#### **DEPARTMENT OF THE INTERIOR**

#### Fish and Wildlife Service

[FWS-R8-ES-2015-N123; FF08ENVD00-FXES11120888ENR0-156]

Endangered and Threatened Wildlife and Plants; Nevada Department of Wildlife; Application for Enhancement of Survival Permit; Proposed Programmatic Candidate Conservation Agreement With Assurances for the Relict Leopard Frog; Clark County, Nevada

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Receipt of application; request for comment.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service) announce receipt from the Nevada Department of Wildlife (NDOW) of an application for an enhancement of survival permit (permit) under the Endangered Species Act of 1973, as amended (ESA). The requested permit would authorize take of the relict leopard frog (RLF) resulting from certain land use and conservation activities, should the species be listed as endangered or threatened in the future. The permit application includes a proposed programmatic candidate conservation agreement with assurances (CCAA) between NDOW and the Service. The requested term of the proposed CCAA and permit is 30 years. In accordance with the requirements of the National Environmental Policy Act (NEPA), we have prepared a draft loweffect screening form supporting our determination that the proposed action qualifies as a categorical exclusion under NEPA. We are accepting comments on the permit application, proposed CCAA, and draft NEPA compliance documentation.

**DATES:** Written comments on the permit application, proposed programmatic CCAA, and draft NEPA compliance documentation must be received on or before August 19, 2015.

ADDRESSES: Obtaining Documents:
Persons wishing to review the
application, the proposed CCAA, the
draft NEPA compliance documentation,
or other related documents may obtain
copies by written or telephone request
to Jeri Krueger, by mail at U.S. Fish and
Wildlife Service, Reno Fish and Wildlife
Office, 1340 Financial Boulevard, Suite
234, Reno, NV 89502, or by phone at
775–861–6300. Copies of these
documents may also be obtained on the
Internet at http://www.fws.gov/nevada/
protected\_species/amphibians/species/
relict leopard frog.html.

Submitting Comments: Please address written comments to Michael J. Senn, Field Supervisor, U.S. Fish and Wildlife Service, Southern Nevada Fish and Wildlife Office, 4701 North Torrey Pines Drive, Las Vegas, NV 89130. You may also send comments by facsimile to 702–515–5231. Please note that your information request or comment is in reference to the Programmatic CCAA for the Relict Leopard Frog, Clark County, Nevada.

FOR FURTHER INFORMATION CONTACT: Jeri Krueger, Reno Fish and Wildlife Office, at the address or telephone number listed above under ADDRESSES.

#### SUPPLEMENTARY INFORMATION:

#### **Document Availability**

You may obtain copies of the permit application, proposed CCAA, draft NEPA compliance documentation, and other related documents from the individual listed under FOR FURTHER INFORMATION CONTACT. Copies of these documents are also available for public inspection, by appointment, during regular business hours (8 a.m. to 4:30 p.m.), at the Southern Nevada Fish and Wildlife Office, 4701 North Torrey Pines Drive, Las Vegas, NV 89130.

#### **Background Information**

Enhancement of survival permits issued for CCAAs encourage non-Federal landowners to implement conservation measures for species that are, or are likely to become, candidates for Federal listing as endangered or threatened by assuring landowners they will not be subjected to increased property use restrictions if the covered species becomes listed in the future. Application requirements and issuance criteria for enhancement of survival permits issued for CCAAs are in the Code of Federal Regulations (CFR) at 50 CFR 17.22(d) and 17.32(d). The policy

for CCAAs was published in the **Federal Register** on June 17, 1999 (64 FR 32726).

#### Proposed Project

The proposed RLF CCAA is a programmatic agreement between the Service and NDOW to further the conservation of the RLF on non-Federal lands or on lands under the management authority of a non-Federal entity. A RLF Conservation Agreement and Strategy (CAS) that directs the implementation of conservation actions on Federal land was completed and approved in 2005, and is being implemented by the RLF Conservation Team, which is comprised of representatives from the signatory agencies of the CAS. One of the primary goals of the CAS is to establish additional populations of RLF within its historic range to secure species persistence into the future. However, the CAS does not provide a mechanism to establish populations on non-Federal lands while providing regulatory assurances to the landowner in the event the species becomes listed in the future. The proposed programmatic CCAA would provide these assurances to non-Federal landowners, thus promoting opportunities to implement conservation actions and increase RLF distribution on non-Federal land.

Under the proposed RLF CCAA, NDOW would establish a program in which individual landowners would enroll their property. To enroll in the program, a landowner would enter into a cooperative agreement (CA) with NDOW that contains a site-specific management plan for the enrolled lands. NDOW would then issue the landowner a Certificate of Inclusion that would authorize a certain level of take of RLF under NDOW's permit as described in the CCAA and CA if the species becomes listed under the ESA in the future. The CA would specify conservation measures to address known threats to the RLF which may include, but are not limited to, translocation of RLF, fencing, deepening a tank or pool, removal of non-native aquatic predators, maintenance of suitable habitat conditions, enhancement of dispersal corridors, vegetation enhancement, and public education. The CA would also specify measures to minimize the incidental take of RLF that might occur as a result of implementing the conservation measures or conducting other land use activities.

NDOW seeks to enroll lands in Clark County, Nevada, that are associated with the Virgin, Muddy, and Colorado River drainages within or in close proximity to the historic range of the RLF, identified as the Potential Management Zone in the CAS and CCAA. The proposed CCAA would include properties that have existing, historic, or potentially suitable habitat for RLF. Such habitats may include reliable and protected water supplies and water quality, limited or controllable public access, accessibility for management actions and RLF translocations or removal, permanent ponds and/or wetland areas, natural springs, spring outflows or reaches of springbrooks and streams that represent suitable habitat for any or all life stages of RLF. An enrolled property may include all or some combination of suitable habitat types, or the potential to create those habitats.

As required by NEPA, we evaluated impacts to the human environment that would result from issuance of the requested permit, and we do not foresee any significant effects. Therefore, we are proposing to categorically exclude this action from further analysis under NEPA. Entering into a cooperative agreement is strictly a voluntary action for landowners, and the activities to be covered under the permit are generally activities already occurring on these properties.

We will evaluate the permit application, associated documents, and comments we receive to determine whether the permit application meets the requirements of the ESA, NEPA, and implementing regulations. If we determine that all requirements are met, we will sign the proposed CCAA and issue a permit under section 10(a)(1)(A) of the ESA to NDOW for take of RLF. We will not make our final decision until after the end of the 30-day public comment period, and we will fully consider all comments we receive during the public comment period.

#### **Public Availability of Comments**

All comments we receive become part of the public record. Requests for copies of comments will be handled in accordance with the Freedom of Information Act, NEPA, and Service and Department of Interior policies and procedures. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee we will be able to do so.

#### Authority

We provide this notice under section 10(c) of the Act (16 U.S.C. 1531 et seq.) and its implementing regulations (50 CFR 17.22 and 17.32), and the National Environmental Policy Act (42 U.S.C. 4371 et seq.) and its implementing regulations (40 CFR 1506.6).

Dated: July 14, 2015.

#### Michael J. Senn,

Field Supervisor, Southern Nevada Fish and Wildlife Office, Las Vegas, Nevada.

[FR Doc. 2015–17705 Filed 7–17–15; 8:45 am]

BILLING CODE 4310-55-P

#### **DEPARTMENT OF THE INTERIOR**

#### U.S. Geological Survey

#### National Earthquake Prediction Evaluation Council

AGENCY: U.S. Geological Survey,

Interior.

**ACTION:** Notice of meeting.

SUMMARY: Pursuant to Public Law 106–503, the National Earthquake Prediction Evaluation Council (NEPEC) will hold its next meeting at the Southern Methodist University in Dallas, Texas. The Committee is comprised of members from academia, industry, and State government. The Committee shall advise the Director of the U.S. Geological Survey (USGS) on matters relating to the USGS's participation in the National Earthquake Hazards Reduction Program.

At the meeting, the Council will receive briefings and updates on: The USGS's strategic plan for operational earthquake forecasting and outcomes of a user-needs workshop on that subject held in March 2015; on USGS work to calculate the probability of future earthquakes in areas of the U.S. subject to induced seismicity; on the estimation of aftershock probabilities and on new modeled estimates of earthquake likelihood along the Wasatch fault zone by a technical working group; and on development of a plan for rapid communication of earthquake information in the Cascadia region. The NEPEC will review USGS procedures for calculating and communicating aftershock probabilities following large earthquakes in areas outside of California and the application of these procedures following the M7.8 Gorkha, Nepal earthquake of April 2015. The council will also finalize a statement for public release summarizing the proper procedures for posing and testing earthquake predictions and forecasts.

Meetings of the National Earthquake Prediction Evaluation Council are open to the public. A draft meeting agenda is available upon request from the Executive Secretary on request (contact information below). In order to ensure sufficient seating and hand-outs, it is requested that visitors pre-register by September 13. Members of the public wishing to make a statement to the Council should provide notice of that intention by August 26 so that time may be allotted in the agenda. A meeting summary will be posted by September 30 to the committee Web site: http://earthquake.usgs.gov/aboutus/nepec/.

DATES: September 2, 2015, commencing at 2:00 p.m. in Room 190 in the Crow Building on the SMU campus and adjourning at 6:00 p.m. September 3, 2015, commencing at 9:00 a.m. in Room 220 (Earnst & Young Gallery) in the Fincher Building on campus and adjourning at 5:00 p.m.

Contact: Dr. Michael Blanpied, U.S. Geological Survey, MS 905, 12201 Sunrise Valley Drive, Reston, Virginia 20192, (703) 648–6696, mblanpied@usgs.gov.

#### Michael L. Blanpied,

Associate Coordinator, USGS Earthquake Hazards Program.

[FR Doc. 2015–17641 Filed 7–17–15; 8:45 am] **BILLING CODE P** 

#### DEPARTMENT OF THE INTERIOR

#### Geological Survey

#### Scientific Earthquake Studies Advisory Committee Meeting

**AGENCY:** U.S. Geological Survey. **ACTION:** Notice of meeting.

SUMMARY: Pursuant to Public Law 106–503, the Scientific Earthquake Studies Advisory Committee (SESAC) will hold its next meeting in the Southern California Earthquake Center (SCEC) Boardroom at the University of Southern California in Los Angeles, California. The Committee is comprised of members from academia, industry, and State government. The Committee shall advise the Director of the U.S. Geological Survey (USGS) on matters relating to the USGS's participation in the National Earthquake Hazards Reduction Program.

The Committee will receive reports on the status of activities of the Program and progress toward Program goals and objectives. The Committee will assess this information and provide guidance on the future undertakings and direction of the Earthquake Hazards Program. Focus topics for this meeting include a program review and strategic planning for 2016–2018.

Meetings of the Scientific Earthquake Studies Advisory Committee are open to the public.

**DATES:** January 28–29, 2015, commencing at 9 a.m. on the first day and adjourning at 5 p.m. on January 29, 2015.

FOR FURTHER INFORMATION CONTACT: Dr. William Leith, U.S. Geological Survey, MS 905, 12201 Sunrise Valley Drive, Reston, Virginia 20192, (703) 648–6786, wleith@usgs.gov.

#### William Leith,

Senior Science Advisor for Earthquake and Geologic Hazards.

[FR Doc. 2015–17640 Filed 7–17–15; 8:45 am]

BILLING CODE 4310-Y7-P

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-962]

#### Certain Resealable Packages With Slider Devices; Institution of Investigation

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 17, 2015, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Reynolds Presto Products Inc. of Appleton, Wisconsin. A supplement to the complaint was filed on July 8, 2015. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain resealable packages with slider devices by reason of infringement of certain claims of U.S. Patent Reexamination Certificate No. 6,427,421 C1 ("the '421 patent"); U.S. Patent No. 6,524,002 ("the '002 patent"); and U.S. Patent No. 7,311,443 ("the '443 patent"). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a general exclusion order, or in the alternative, a limited exclusion order, and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade

Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205-2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205-2000. General information concerning the Commission may also be obtained by accessing its internet server at http://www.usitc.gov. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at http://edis.usitc.gov.

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

**Authority:** The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2015).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on July 14, 2015, ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain resealable packages with slider devices by reason of infringement of one or more of claim 39 of the '421 patent; claim 1 of the '002 patent; and claim 1 of the '443 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Reynolds Presto Products Inc., 670 N. Perkins Street, Appleton, WI 54912.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served: Inteplast Group, Ltd., 9 Peach Tree Hill

Road, Livingston, NJ 07039. Minigrip, LLC, 161 Kimball Bridge Road, Alpharetta, GA 30009.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and (3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission. Issued: July 15, 2015.

#### Jennifer Rohrbach,

Supervisory Attorney.

[FR Doc. 2015–17716 Filed 7–17–15; 8:45 am]

BILLING CODE 7020-02-P

#### **DEPARTMENT OF JUSTICE**

#### Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On July 15, 2015, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Northern District of Iowa in the lawsuit entitled *United States*, et al. v. Interstate Power and Light Company, Civil Case No. 1:15—cv—00061 (N.D. Iowa). The State of Iowa, Linn County Iowa, and the Sierra Club are coplaintiffs in the case.

In this civil enforcement action under the federal Clean Air Act ("Act"), the United States alleges that Interstate Power and Light Company ("Defendant"), failed to comply with certain requirements of the Act intended to protect air quality at power plants in Iowa. The complaint seeks injunctive relief and civil penalties for violations of the Clean Air Act's Prevention of Significant Deterioration ("PSD") provisions, 42 U.S.C. 7470–92, and various Clean Air Act implementing regulations. Specifically, the complaint alleges that Defendant failed to obtain appropriate permits and failed to install and operate required pollution control devices to reduce emissions of sulfur dioxide ("SO<sub>2</sub>") and/or nitrogen oxides ("NO<sub>X</sub>") at the company's Ottumwa and Lansing plants.

The proposed Consent Decree would resolve violations for certain provisions of the Act at the Ottumwa and Lansing plants as well as Defendant's five other coal-fired power plants in Iowa: The Burlington, Dubuque, M.L. Kapp, Prairie Creek, and Sutherland plants. The proposed Consent Decree would require the Defendant to reduce harmful  $SO_2$ , NO<sub>X</sub>, and particulate matter emissions from these seven plants through the installation and operation of pollution controls and conversions to natural gas or retirements. The Defendant will also spend \$6,000,000 to fund environmental mitigation projects that will further reduce emissions and benefit communities adversely affected by the pollution from the plants, and pay a civil penalty of \$1,100,000.

The publication of this notice opens a period for public comment on the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States, et al. v. Interstate Power and Light Company,* Civil Case No. 1:15–cv&00061 (N.D. Iowa), D.J. Ref. No. 90–5–2–1–10594. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	Send them to:
By email	pubcomment- ees.enrd@usdoj.gov. Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Consent Decree may be examined and downloaded at this Justice Department Web site: http://www.justice.gov/enrd/consent-decrees. We will provide a paper copy of the proposed Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library,

U.S. DOJ-ENRD, P.O. Box 7611, Washington, DC 20044-7611.

Please enclose a check or money order for \$ 29.50 (25 cents per page reproduction cost) payable to the United States Treasury.

#### Maureen Katz.

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015–17711 Filed 7–17–15; 8:45 am]

BILLING CODE 4410-15-P

#### **DEPARTMENT OF JUSTICE**

[OMB Number 1125—NEW]

Agency Information Collection Activities; Proposed eCollection; eComments Requested; Unfair Immigration-Related Employment Practices Complaint Form

**AGENCY:** Executive Office for Immigration Review, Department of Justice.

**ACTION:** 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for Immigration Review, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the Federal Register at 80 FR 29340, on May 21, 2015, allowing for a 60 day comment period.

**DATES:** Comments are encouraged and will be accepted for an additional 30 days until August 19, 2015.

FOR FURTHER INFORMATION CONTACT: If vou have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Charles Adkins-Blanch, Acting General Counsel, Executive Office for Immigration Review, U.S. Department of Justice, Suite 2600, 5107 Leesburg Pike, Falls Church, Virginia 20530; telephone: (703) 305-0470. Written comments and/ or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to OIRA submissions@ omb.eop.gov.

**SUPPLEMENTARY INFORMATION:** Written comments and suggestions from the public and affected agencies concerning the proposed collection of information

are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

Enhance the quality, utility, and clarity of the information to be collected; and/or

-Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

#### **Overview of This Information** Collection

1. Type of Information Collection: New Voluntary Collection.

2. The Title of the Form/Collection: Unfair Immigration-Related Employment Practices Complaint Form.

 The agency form number, if any, and the applicable component of the Department sponsoring the collection: Form EOIR-58. The applicable component within the Department of Justice is the Office of the Chief Administrative Hearing Officer (OCAHO), Executive Office for Immigration Review.

4. Äffected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals who wish

to file a complaint alleging unfair immigration-related employment practices under section 274B of the Immigration and Nationality Act (INA). Other: None. Abstract: Section 274B of the INA prohibits: employment discrimination on the basis of citizenship status or national origin; retaliation or intimidation by an employer against an individual seeking to exercise his or her rights under this section; and "document abuse" or overdocumentation by the employer, which occurs when the employer asks an applicant or employee for more or different documents than required for employment eligibility verification under INA section 274A, with the intent of discriminating against the employee in violation of section 274B. Individuals who believe that they have suffered discrimination in violation of section

274B may file a charge with the

Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC). The OSC then has 120 days to determine whether to file a complaint with OCAHO on behalf of the individual charging party. If the OSC chooses not to file a complaint, the individual may then file his or her own complaint directly with OCAHO. This information collection may be used by an individual to file his or her own complaint with OCAHO. The Form EOIR-58 will elicit, in a uniform manner, all of the required information for OCAHO to assign a section 274B complaint to an Administrative Law Judge for adjudication.

5. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: It is estimated that 22 respondents will complete the form annually; each response will be completed in approximately 30 minutes.

6. An estimate of the total public burden (in hours) associated with the collection: The estimated public burden associated with this collection is 11 hours. It is estimated that 22 forms will be received, taking 30 minutes to

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: July 15, 2015.

#### Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015-17697 Filed 7-17-15; 8:45 am]

BILLING CODE 4410-30-P

#### **DEPARTMENT OF LABOR**

#### **Employment and Training** Administration

#### **Trade Adjustment Assistance** Program; Designation of Certifying Officers

**AGENCY:** Employment and Training Administration, Labor.

**ACTION:** Notice.

**SUMMARY:** This notice is to designate Certifying Officers to carry out functions under the Trade Adjustment Assistance (TAA) program under chapter 2 of title II of the Trade Act of 1974, as amended (19 U.S.C. 2271 et seq.), and the implementing regulations at 29 CFR part 90.

Background: The TAA program operates under the Trade Act of 1974, as amended, to provide assistance to domestic workers adversely affected in their employment by certain types of foreign trade. Workers become eligible for program benefits only if the worker group is certified under the Act as eligible to apply for adjustment assistance. From time to time the agency issues an Order designating or redesignating officials of the agency authorized to act as Certifying Officers, responsible for reviewing and signing adjustment assistance determinations. This also is done when current Certifying Officials retire or leave and/ or when there is a need to designate new Certifying Officials. Employment and Training Order No. 1-15 was issued to revise the listing of officials designated as Certifying Officers, superseding Employment and Training Order No. 1-11 (76 FR 2720, January 14, 2011). The Employment and Training Order No. 1-XX is published below. FOR FURTHER INFORMATION CONTACT:

Norris T. Tyler III, 202-693-3651.

#### SUPPLEMENTARY INFORMATION:

## Employment and Training Order No. 1-

TO: National and Regional Offices FROM: Portia WU, Assistant Secretary for Employment and Training SUBJECT: Trade Adjustment Assistance Program (Trade Act of 1974)— Designation of Certifying Officers

- 1. Purpose. To designate Certifying Officers to carry out functions under the Trade Adjustment Assistance (TAA) program under chapter 2 of title II of the Trade Act of 1974, as amended (19 U.S.C. 2271 et seq.), and the implementing regulations at 29 CFR part
- 2. Directive Affected. Employment and Training Order No. 1-11 (76 FR 2720, January 14, 2011), which designated Certifying Officers, is cancelled and superseded.
- 3. Background. Regulations at 29 CFR part 90 vest persons designated as Certifying Officers with the authority and responsibility to make determinations and redeterminations and to issue certifications of eligibility of groups of workers to apply for adjustment assistance under the TAA

4. Designation of Officials. By virtue of my authority under Secretary's Order No. 6-2010, October 20, 2010 (75 FR 66267, October 27, 2010), I designate or redesignate as Certifying Officers for the TAA program:

a. Jessica R. Webster, Program Analyst, Office of Trade Adjustment Assistance

- b. Jacquelyn R. Mendelsohn, Program Analyst, Office of Trade Adjustment Assistance
- c. Hope D. Kinglock, Program Analyst, Office of Trade Adjustment Assistance
- d. DelMin A. Chen, Program Analyst, Office of Trade Adjustment Assistance
- e. Norris T. Tyler III, Director, Office of Trade Adjustment Assistance

The foregoing officials are delegated authority and assigned responsibility, subject to the general direction and control of the Assistant Secretary and Deputy Assistant Secretaries of the Employment and Training Administration, and the Administrator of the Office of Trade Adjustment Assistance or the successor office, to carry out the duties and functions of Certifying Officers under 29 CFR part 90 and any succeeding regulations.

5. *Effective Date*. This order is effective on date of issuance.

This order rescinds ETO 1–11. This Employment and Training Order No. 1–15 was signed by Portia Wu on

7/7/15.

Dated: Signed the 7th day of July 2015.

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2015–17721 Filed 7–17–15; 8:45 am]

BILLING CODE 4510-FN-P

Portia Wu.

#### **DEPARTMENT OF LABOR**

## Office of Labor-Management Standards

Agency Information Collection Activities; Information Collection Request; Labor Organization and Auxiliary Reports Comment Period Extension

**AGENCY:** Office of Labor-Management Standards, Department of Labor.

**ACTION:** Notice.

**SUMMARY:** This document extends the period for comments on the proposal, published on May 20, 2015 (80 FR 29096), to amend the information collection request 1245-0003, particularly the Form LM-2, LM-3, and LM–4 Labor Organization Annual Report instructions, to require filers of such reports to submit the reports electronically, and to modify the hardship exemption process for Form LM-2 filers. The comment period, which was to expire on July 20, 2015, is extended to August 19, 2015. A copy of the proposed information collection request can be obtained by contacting the office listed below in the addresses section of this Notice.

**DATES:** Written comments on the proposal to amend the information collection request 1245–0003, published on May 20, 2015 (80 FR 29096), must be submitted to the office listed in the addresses section below on or before August 19, 2015.

ADDRESSES: Andrew R. Davis, Chief of the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–5609, Washington, DC 20210, olms-public@dol.gov, (202) 693–0123 (this is not a toll-free number), (800) 877–8339 (TTY/TDD).

Please use only one method of transmission (mail or submission via www.regulations.gov using RIN: 1245—AA06) to submit comments or to request a copy of this information collection and its supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden. You may also request a copy of this information collection and its supporting documentation by sending an email to olms-public@dol.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 20, 2015 (80 FR 29096), the Department sought public comments on the proposal to amend Labor Organization and Auxiliary Reports information collections approved under OMB Control Number 1245–0003, specifically the Form LM-3 and LM-4 instructions, to require mandatory electronic filing of these reports, as well as modify the Form LM-2 hardship exemption process to correspond with that proposed for the Form LM-3 and LM-4 reports, which would only permit temporary hardship exemption submissions, not continuing. As stated in the notice, the Department believes that reasonable changes must be made to the means by which the forms required under the Labor-Management Reporting and Disclosure Act (LMRDA) Title II are filed. The most efficient way to provide meaningful access to this information by interested members of the public is to require that the reports filed by small and mediumsized labor organizations be filed in electronic form. This change will benefit the filers, union members, and the public, as well as the Department.

Interested persons were invited to submit comments on or before July 20, 2015, 60 days after the publication of the original notice. A public commenter has requested a 30-day extension of time to submit comments. In response to these requests, the Department has decided to extend the comment period for an additional 30 days. Comments on

the proposed information collection must be received on or before August 19, 2015. An extension of this duration is appropriate, because it will afford parties a meaningful opportunity to submit comments on the proposal without unduly delaying final action on the proposed regulation.

Dated: July 15, 2015.

#### Andrew R. Davis,

Chief, Division of Interpretations and Standards, Office of Labor-Management Standards.

[FR Doc. 2015-17731 Filed 7-17-15; 8:45 am]

BILLING CODE 4510-86-P

## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

#### **National Endowment for the Arts**

#### **Arts Advisory Panel Meetings**

**AGENCY:** National Endowment for the Arts, National Foundation on the Arts and Humanities.

**ACTION:** Notice of meetings.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that three meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

**DATES:** All meetings are Eastern time and ending times are approximate:

Literature (review of applications): This meeting will be closed.

Date and time: August 4, 2015; 3 p.m. to 5 p.m.

Literature (review of applications): This meeting will be closed.

Date and time: August 5, 2015; 3 p.m. to 5 p.m.

Design (review of applications): This meeting will be closed.

Date and time: August 24, 2015; 3 p.m. to 5 p.m.

**ADDRESSES:** National Endowment for the Arts, Constitution Center, 400 7th St. SW., Washington, DC 20506.

#### FOR FURTHER INFORMATION CONTACT:

Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; plowitzk@arts.gov, or call 202/682–5691.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in

confidence to the agency. In accordance with the determination of the Chairman of February 15, 2012, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5. United States Code.

Dated: July 14, 2015.

#### Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 2015–17679 Filed 7–17–15; 8:45 am] BILLING CODE 7537–01–P

#### NATIONAL SCIENCE FOUNDATION

## Sunshine Act Meetings; National Science Board

The National Science Board's Committee on Strategy and Budget (CSB), pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

**DATE & TIME:** Tuesday July 28, 2015 at 3:00–4:00 p.m. EDT.

**SUBJECT MATTER:** Discussion of the NSF's FT 2017 budget development. **STATUS:** Closed.

This meeting will be held by teleconference. Please refer to the National Science Board Web site for additional information and schedule updates (time, place, subject matter or status of meeting), which may be found at <a href="http://www.nsf.gov/nsb/notices/">http://www.nsf.gov/nsb/notices/</a>. Point of contact for this meeting is Elise Lipkowitz (elipkowi@nsf.gov).

Dated: July 16, 2015.

#### Suzanne Plimpton,

Management Analyst.

[FR Doc. 2015-17868 Filed 7-16-15; 4:15 pm]

BILLING CODE 7555-01-P

#### NATIONAL SCIENCE FOUNDATION

#### Notice of Intent To Seek Approval To Establish an Information Collection

**AGENCY:** National Science Foundation. **ACTION:** Notice and request for comments.

SUMMARY: Under the Paperwork Reduction Act of 1995, Public Law 104– 13 (44 U.S.C. 3501 et seq.), and as part of its continuing effort to reduce paperwork and respondent burden, the National Science Foundation (NSF) is inviting the general public or other Federal agencies to comment on this proposed continuing information collection.

Comments are invited on whether the proposed collection of information is necessary for the proper performance of the functions of the Foundation, including whether the information will have practical utility; the accuracy of the Foundation's estimate of the burden of the proposed collection of information; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

**DATES:** Written comments on this notice must be received by September 18, 2015, to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to address below.

FOR FURTHER INFORMATION CONTACT: Ms. Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 1265, Arlington, Virginia 22230; telephone (703) 292–7556; or send email to splimpto@nsf.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

#### SUPPLEMENTARY INFORMATION:

Title of Collection: Community College Innovation Challenge Information Collection.

OMB Number: 3145—NEW. Expiration Date of Approval: Not applicable.

Type of Request: Intent to seek approval to establish an information collection for post-challenge outcome monitoring system.

#### Abstract

Proposed Project

NSF provides nearly 20 percent of federal funding for basic research to academic institutions.¹ The Office of Legislative and Public Affairs (OLPA) communicates information about the activities, programs, research results and policies of NSF. OLPA employs a wide variety of tools and techniques to engage the general public and selected audiences including Congress, the news media, state and local governments, other Federal agencies, and the research and education communities. To these

ends, OLPA provides support for innovative new initiatives designed to increase public engagement and scientific progress. An important aspect of scientific progress is the education of future scientists. Improvements in science, technology, engineering and mathematics (STEM) curricula, particularly changes that engage students in the process of research and discovery, have become a focal point for attracting more students into science. Undergraduate research is a significant strategy for improving undergraduate STEM education.

Community colleges prepare technicians who will become an integral part of research efforts and students who will continue their education at four-year institutions. Further, they play a significant role in the preparation of underrepresented groups in science. Community colleges have long recognized the importance of mentoring students and have a history of success in educating underrepresented students for successful careers in STEM. Thus, community colleges play an important role in workforce development in their states and local communities. Industry frequently looks to community colleges to provide an educated and technologically up-to-date workforce. The National Science Foundation's (NSF) thrust of incorporating research into the traditional teaching mission of the community college is a relatively new expansion of its mission. This challenge furthers NSF's mission by enabling students to discover and demonstrate their capacity to use science to make a difference in the world, and to transfer knowledge into action.

The Office of Legislative and Public Affairs (OLPA) requests of the Office of Management and Budget (OMB) an approval for an information collection intended to monitor outputs, short-term, intermediate and long term outcomes of OLPA's new Community College Innovation Challenge.

The survey questionnaire, individually tailored to measure outputs and outcomes for this initiative, will provide essential information for program monitoring purposes. Data collected by this collection will be used for program planning, management, and evaluation. A summary of monitoring data can be used to respond to queries from Congress, the public, NSF's external merit reviewers who serve as advisors, including Committees of Visitors (COVs), and NSF's Office of the Inspector General. These data are needed for effective administration, program and project monitoring, evaluation, and for measuring

<sup>&</sup>lt;sup>1</sup> National Science Foundation. (2012). NSF at a glance. Retrieved from http://www.nsf.gov/about/glance.jsp.

attainment of NSF's program and strategic goals, as identified by the President's Accountable Government Initiative, the Government Performance and Results Act (GPRA) Modernization Act of 2010, and NSF's Strategic Plan. The collection included in this request is designed to assist in management of the CCIC and to serve as a data resource for current and future initiative evaluations.

This data collection effort will enable OLPA to longitudinally monitor outputs and outcomes given the unique goals and purpose of the CCIC. This is very important to enable appropriate and

accurate evidence-based management of the program and to determine whether or not the specific goals of the program are being met.

Participants will be invited to submit this information via data collection methods that include but are not limited to online surveys, interviews, phone interviews, etc. The indicators are both quantitative and descriptive and may include number of students majoring in STEM disciplines or joining the STEM workforce, faculty expressions of mentoring ability for STEM careers, number of participants continuing to participate in innovation or

entrepreneurship activities among other indicators.

Use of the Information: The data collected will be used for NSF internal reports, historical data, program level studies and evaluations, and for securing future funding for the CCIC program maintenance and growth.

These data could be used for program evaluation purposes if deemed necessary. Evaluation designs could make use of metadata associated with the contest, and other characteristics to identify a comparison group to evaluate the impact of the program funding and other interesting research questions.

#### **ESTIMATE OF BURDEN**

Collection title	Number of respondents Annual number of responses/ respondent		Annual hour burden
Community College Innovation Challenge Monitoring Collection	410	.25	.1
Total	410	.25	10.25

Below is an example that shows how the hour burden was estimated for the monitoring system.

The estimated average number of annual respondents is 410, with an estimated annual response burden of 10.25 hours. For post-award monitoring systems, OLPA expects to collect data at 6 months 1, 3, and 8 years postchallenge, in order to have the best chance of capturing the more immediate outcomes expected by ~1 year postchallenge, intermediate outcomes at 3 years post-challenge, and long-term outcomes/impacts at 8 years post challenge. These four (4) data collections spread over the span of 10 years; this averages to 0.25 data collections/year. The community

college population may transition relatively quickly to another school or to the workforce and we might expect a shorter and more condensed timeline of outcomes and impacts. Thus, we wish to collect data at 6 months and one year after the challenge, and then once annually at 3 and 8 years post-award.

#### Respondents

The respondents are faculty mentors and community college students.

Estimates of Annualized Cost to Respondents for the Hour Burdens

The overall annualized cost to the respondents is estimated to be \$8,800. The following table shows the annualized estimate of costs to faculty

mentor respondents, who are community college professors. This estimated hourly rate is based on a report from the American Association of University Professors, "Annual Report on the Economic Status of the Profession, 2014-15," Academe, March-April 2015, Survey Report Table 4. According to this report, the average salary of an associate professor across all types of associate's degree granting institutions (public, privateindependent) was \$62,221. When divided by the number of standard annual work hours (2,080), this calculates to approximately \$30 per hour. For the students, due to the broad range of employment levels, we estimated an average hourly rate of \$20.

Respondent type	Number of respondents	Burden hours per respondent	Average hourly rate	Estimated annual cost
Faculty Mentors	60 350	1 1	\$30 20	\$1,800 7,000

#### Estimated Number of Responses per Report

Data collection involves all finalists and semifinalists in the challenge. The

table below shows the total universe and sample size for the collections.

#### RESPONDENT UNIVERSE AND SAMPLE SIZE OF CCIC INFORMATION COLLECTIONS

Collection title	Universe of respondents	Sample size
Community College Innovation Challenge Monitoring Collection		410

Dated: July 15, 2015.

#### Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2015–17698 Filed 7–17–15; 8:45 am]

BILLING CODE 7555-01-P

### NUCLEAR REGULATORY COMMISSION

[NRC-2015-0001]

#### **Sunshine Act Meeting Notice**

**DATE:** July 20, 27, August 3, 10, 17, 24, 2015.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

#### Week of July 20, 2015

There are no meetings scheduled for the week of July 20, 2015.

#### Week of July 27, 2015—Tentative

There are no meetings scheduled for the week of July 27, 2015.

#### Week of August 3, 2015—Tentative

Thursday, August 6, 2015

9:30 a.m. Strategic Programmatic Overview of the Operating Reactors Business Line (Public Meeting) (Contact: Nathan Sanfilippo: 301– 415–8744)

This meeting will be webcast live at the Web address—http://www.nrc.gov/. 1:00 p.m. Discussion of Management and Personnel Issues (Closed—Ex. 2 & 6)

#### Week of August 10, 2015—Tentative

Thursday, August 13, 2015

9:00 a.m. Briefing on Greater-Than-Class-C Low-Level Radioactive Waste (Public Meeting) (Contact: Gregory Suber—301–415–8087)

This meeting will be webcast live at the Web address—http://www.nrc.gov/.

#### Week of August 17, 2015—Tentative

There are no meetings scheduled for the week of August 17, 2015.

#### Week of August 24, 2015—Tentative

There are no meetings scheduled for the week of August 24, 2015.

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Glenn Ellmers at 301–415–0442 or via email at Glenn.Ellmers@nrc.gov.

\* \* \* \* \*

The NRC Commission Meeting Schedule can be found on the Internet at: http://www.nrc.gov/public-involve/public-meetings/schedule.html.

\* \* \* \* \*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0727, by videophone at 240-428-3217, or by email at Kimberly.Mever-Chambers@nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email Brenda. Akstulewicz@nrc.gov or Patricia. Jimenez@nrc.gov.

Dated: July 16, 2015.

#### Richard J. Laufer,

Technical Coordinator, Office of the Secretary.

[FR Doc. 2015–17823 Filed 7–16–15; 4:15 pm]

BILLING CODE 7590-01-P

### NUCLEAR REGULATORY COMMISSION

[Docket Nos. 052-00027 and 052-00028; NRC-2008-0441]

### Virgil C. Summer Nuclear Station, Units 2 and 3

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** License amendment application; opportunity to comment, request a hearing, and petition for leave to intervene; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the Federal Register on July 9, 2015, that gave notice to the public that it is considering issuance of an amendment to Combined Licenses (NPF–93 and NPF–94), issued to South Carolina Electric and Gas (SCE&G) and South Carolina Public Service Authority, for construction and operation of the Virgil C. Summer Nuclear Station, Units 2 and 3 located in Fairfield County, South Carolina. This action is being taken to correct the

date by which a request for a hearing or a petition for leave to intervene must be filed.

**DATES:** This correction is effective on July 20, 2015.

ADDRESSES: Please refer to Docket ID NRC-2008-0441 when contacting the NRC about the availability of information regarding this action. You may obtain publicly-available information related to this action using any of the following methods:

- Federal Rulemaking Web site: Go to http://www.regulations.gov and search for Docket ID NRC-2008-0441. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.
- NRC's Agencywide Documents
  Access and Management System
  (ADAMS): You may obtain publiclyavailable documents online in the
  ADAMS Public Documents collection at
  http://www.nrc.gov/reading-rm/
  adams.html. To begin the search, select
  "ADAMS Public Documents" and then
  select "Begin Web-based ADAMS
  Search." For problems with ADAMS,
  please contact the NRC's Public
  Document Room (PDR) reference staff at
  1–800–397–4209, 301–415–4737, or by
  email to pdr.resource@nrc.gov.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

#### FOR FURTHER INFORMATION CONTACT:

Denise McGovern, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555– 0001; telephone: 301–415–0681; email: Denise.Mcgovern@nrc.gov.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 9, 2015 (80 FR 39450), in FR Doc. 2015–16797, on page 39450, third column, the **DATES** Section should be revised to read as follows: "Submit comments by August 10, 2015. Request for a hearing or petition for leave to intervene must be filed by September 8, 2015."

Dated in Rockville, Maryland, this 14th day of July, 2015.

For the Nuclear Regulatory Commission. Cindy Bladey,

Branch Chief, Rules, Announcements, and Directives Branch, Division of Administration Services, Office of Administration.

[FR Doc. 2015–17677 Filed 7–17–15; 8:45 am]

BILLING CODE 7590-01-P

### NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-18 and 50-183; NRC-2015-0169]

### GE Hitachi Nuclear Energy; Vallecitos Nuclear Center

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Partial site release; public meeting and request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is considering a request from GE Hitachi Nuclear Energy to approve the release from their NRC power reactor licenses of a portion of their Vallecitos Nuclear Center property for unrestricted use. The NRC will approve or deny the request based on its review of the request and the result of an NRC confirmatory survey of the property proposed for release. Approval of the request would allow GE to sell the released portion of the property to a non-GE controlled entity. The NRC is requesting public comment on the contemplated action and invites stakeholders and interested persons to participate. The NRC plans to hold a public meeting to promote full understanding of the contemplated action and facilitate public comment. DATES: Submit comments by October 5, 2015. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date. A public meeting will be held on July 22, 2015. **ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- Federal Rulemaking Web site: Go to http://www.regulations.gov and search for Docket ID NRC-2015-0169. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document
- Mail comments to: Cindy Bladey, Office of Administration, Mail Stop: OWFN-12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the SUPPLEMENTARY INFORMATION section of this document.

**FOR FURTHER INFORMATION CONTACT:** Jack D. Parrott, Senior Project Manager,

Office of Nuclear Material Safety and Safeguards; telephone: 301–415–6634; email: *Jack.Parrott@nrc.gov*; U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

#### SUPPLEMENTARY INFORMATION:

### I. Obtaining Information and Submitting Comments

#### A. Obtaining Information

Please refer to Docket ID NRC–2015– 0169 when contacting the NRC about the availability of information for this action. You may obtain publiclyavailable information related to this action by any of the following methods:

- Federal rulemaking Web site: Go to http://www.regulations.gov and search for Docket ID NRC-2015-0169.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publiclyavailable documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/ adams.html. To begin the search, select 'ADAMS Public Documents'' and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the SUPPLEMENTARY **INFORMATION** section.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

#### I. Background

The U.S. Nuclear Regulatory Commission (NRC) has received, by letter dated April 24, 2015 (ADAMS Accession No. ML15114A437), a request from GE Hitachi Nuclear Energy (GE or licensee), to approve a partial site release of its Vallecitos Nuclear Center (VNC) site located at 6705 Vallecitos Rd, Sunol, California. The VNC site contains two facilities licensed as power reactors under part 50, "Domestic Licensing of Production and Utilization Facilities," of Title 10 of the Code of Federal Regulations (10 CFR). Both units, Vallecitos Boiling Water Reactor (VBWR), NRC License DPR-1, Docket 50-18, and Empire State Atomic Development Agency Vallecitos Experimental Superheat Reactor (EVESR), NRC License DR-10, Docket 50-183, are shut down per NRC regulations in 10 CFR 50.82(a). These units are in "SAFSTOR" mode awaiting

the termination of the power reactor licenses. In accordance with 10 CFR 50.83, "Release of Part of a Power Reactor Facility or Site for Unrestricted Use," the licensee requests release from the NRC licenses, for unrestricted use, of an approximately 610-acre parcel, in the northern section of the approximately 1,600 acre VNC site. The licensee is declaring the parcel as "nonimpacted" per the definition in 10 CFR 50.2. Approval of the request will allow GE to sell the released portion to a non-GE controlled entity.

The NRC will determine whether the licensee has adequately evaluated the effect of releasing the property per the requirements of 10 CFR 50.83(a)(1), and determine whether the licensee's classification of any released areas as "non-impacted" is adequately justified. If the NRC determines that the licensee's submittal is adequate, the NRC will inform the licensee in writing that the release is approved.

#### II. Public Meeting

The NRC will conduct a public meeting to discuss GE's request for approval of the partial site release.

The meeting will be held on Wednesday, July 22, 2015, from 6:30 p.m. until 8:30 p.m., Pacific Daylight Time, at the Holiday Inn Dublin, 6680 Regional St., Dublin, CA 94568.

This is a Category 3 public meeting where stakeholders are invited to fully engage NRC staff to provide a range of views, information, concerns and suggestions with regard to regulatory issues concerning the proposed action. After the licensee and NRC staff presentation portions of the meeting, the public is allowed to speak and ask questions. Comments can be provided orally or in writing to the NRC staff present at the meeting.

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g., braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240-428-3217, or by email at Kimberly.Meyer-Chambers@ nrc.gov. Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Stakeholders should monitor the NRC's public meeting Web site for information about the public meeting at: http://www.nrc.gov/public-involve/public-meetings/index.cfm. The agenda

will be posted no later than 10 days prior to the meeting.

Dated at Rockville, Maryland, this 10th day of July, 2015.

For the Nuclear Regulatory Commission.

#### Andrew Persinko,

Deputy Director, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2015–17763 Filed 7–17–15; 8:45 am]

BILLING CODE 7590-01-P

#### POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015-68 and CP2015-99; Order No. 2581]

#### **New Postal Product**

**AGENCY:** Postal Regulatory Commission. **ACTION:** Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of International Merchandise Return Service Agreements with Foreign Postal Operators Non-Published Rates to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** Comments are due: July 21, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at http://www.prc.gov. Those who cannot submit comments electronically should contact the person identified in the FOR FURTHER INFORMATION CONTACT section by telephone for advice on filing alternatives.

#### FOR FURTHER INFORMATION CONTACT:

David A. Trissell, General Counsel, at 202–789–6820.

#### SUPPLEMENTARY INFORMATION:

#### **Table of Contents**

I. Introduction II. Notice of Commission Action III. Ordering Paragraphs

#### I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 et seq., the United States Postal Service (Postal Service) filed a formal request and associated supporting information to add Competitive International Merchandise Return Service Agreements with Foreign Postal Operators (IMRS–FPO) to the competitive products list. If the proposed product is approved by the Commission, the Postal Service intends to file each new IMRS–FPO agreement in this docket on or before its effective date, pursuant to 39 U.S.C. 407(d). Request at 5 n.8.

To support its Request, the Postal Service filed an application for non-public treatment of materials filed under seal; a redacted copy of Governors' Decision No. 11–6, which authorizes the product; a set of maximum and minimum prices; a statement of supporting justification, as required by 39 CFR 3020.32; a copy of proposed mail classification schedule language; a copy of the IMRS–FPO model agreement; a certification of compliance with 39 U.S.C. 3633(a); a redacted copy of a related management analysis; and supporting financial workpapers.

In the attached statement of supporting justification, the Postal Service asserts the IMRS-FPO would close a gap in currently available postal product offerings and that the proposed product would generate new revenue and encourage growth in cross-border ecommerce via the postal channel. Id., Attachment 3 at 4. The Postal Service further contends that IMRS-FPO belongs on the competitive products list because it will not be subsidized by market dominant products, covers costs attributable to it, does not cause competitive products as a whole to fail to make the appropriate contribution to institutional costs, is part of a market over which the Postal Service does not exercise market dominance, and is not covered by the postal monopoly. Request at 2-4.

#### **II. Notice of Commission Action**

The Commission establishes Docket Nos. MC2015–68 and CP2015–99 to consider the Request pertaining to the addition of IMRS–FPO to the competitive products list.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than July 21, 2015. The public portions of these filings can be accessed via the Commission's Web site (http://www.prc.gov).

The Commission appoints James F. Callow to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

(IMRS–FPO) Product to the Competitive Products List and Notice of Filing IMRS–FPO Model Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, July 10, 2015 (Request).

#### III. Ordering Paragraphs

It is ordered:

- 1. The Commission establishes Docket Nos. MC2015–68 and CP2015–99 to consider the matters raised in each docket.
- 2. Pursuant to 39 U.S.C. 505, James F. Callow is appointed to serve as Public Representative in these dockets.
- 3. Comments are due no later than July 21, 2015.
- 4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

#### Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015-17686 Filed 7-17-15; 8:45 am]

BILLING CODE 7710-FW-P

### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-75447; File No. SR-NASDAQ-2015-075]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change Relating to the Listing and Trading of Shares of the First Trust SSI Strategic Convertible Securities ETF of First Trust Exchange-Traded Fund IV

July 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b–4 thereunder,² notice is hereby given that on July 2, 2015, The NASDAQ Stock Market LLC ("Nasdaq" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by Nasdaq. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq proposes to list and trade the shares of the First Trust SSI Strategic Convertible Securities ETF (the "Fund") of First Trust Exchange-Traded Fund IV (the "Trust") under Nasdaq Rule 5735 ("Managed Fund Shares").<sup>3</sup> The shares

Continued

<sup>&</sup>lt;sup>1</sup> Request of the United States Postal Service to Add Competitive International Merchandise Return Service Agreements with Foreign Postal Operator

<sup>&</sup>lt;sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>&</sup>lt;sup>2</sup> 17 CFR 240.19b-4.

<sup>&</sup>lt;sup>3</sup> The Commission approved Nasdaq Rule 5735 in Securities Exchange Act Release No. 57962 (June 13, 2008), 73 FR 35175 (June 20, 2008) (SR–NASDAQ–2008–039). There are already multiple actively-managed funds listed on the Exchange; see, e.g., Securities Exchange Act Release Nos. 72506

of the Fund are collectively referred to herein as the "Shares."

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of, and basis for, the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The Exchange proposes to list and trade the Shares of the Fund under Nasdaq Rule 5735, which governs the listing and trading of Managed Fund Shares <sup>4</sup> on the Exchange. The Fund will be an actively-managed exchange-traded fund ("ETF"). The Shares will be offered by the Trust, which was established as a Massachusetts business trust on September 15, 2010. The Trust is registered with the Commission as an investment company and has filed a

(July 1, 2014), 79 FR 38631 (July 8, 2014) (SR–NASDAQ–2014–050) (order approving listing and trading of First Trust Strategic Income ETF); 69464 (April 26, 2013), 78 FR 25774 (May 2, 2013) (SR–NASDAQ–2013–036) (order approving listing and trading of First Trust Senior Loan Fund); and 66489 (February 29, 2012), 77 FR 13379 (March 6, 2012) (SR–NASDAQ–2012–004) (order approving listing and trading of WisdomTree Emerging Markets Corporate Bond Fund). The Exchange believes the proposed rule change raises no significant issues not previously addressed in those prior Commission orders.

<sup>4</sup> A Managed Fund Share is a security that represents an interest in an investment company registered under the Investment Company Act of 1940 (15 U.S.C. 80a–1) (the "1940 Act") organized as an open-end investment company or similar entity that invests in a portfolio of securities selected by its investment adviser consistent with its investment objectives and policies. In contrast, an open-end investment company that issues Index Fund Shares, listed and traded on the Exchange under Nasdaq Rule 5705, seeks to provide investment results that correspond generally to the price and yield performance of a specific foreign or domestic stock index, fixed income securities index or combination thereof.

<sup>5</sup> The Commission has issued an order, upon which the Trust may rely, granting certain exemptive relief under the 1940 Act. See Investment Company Act Release No. 30029 (April 10, 2012) (File No. 812–13795) (the "Exemptive Relief"). In addition, the Commission has issued no-action relief, upon which the Trust may rely, pertaining to the Fund's ability to invest in options contracts, futures contracts and swap agreements notwithstanding certain representations in the application for the Exemptive Relief. See Commission No-Action Letter (December 6, 2012).

registration statement on Form N–1A ("Registration Statement") with the Commission.<sup>6</sup> The Fund will be a series of the Trust. The Fund intends to qualify each year as a regulated investment company ("RIC") under Subchapter M of the Internal Revenue Code of 1986, as amended.

First Trust Advisors L.P. will be the investment adviser ("Adviser") to the Fund. SSI Investment Management Inc. will serve as investment sub-adviser ("Sub-Adviser") to the Fund and provide day-to-day portfolio management. First Trust Portfolios L.P. (the "Distributor") will be the principal underwriter and distributor of the Fund's Shares. The Bank of New York Mellon Corporation ("BNY") will act as the administrator, accounting agent, custodian and transfer agent to the Fund.

Paragraph (g) of Rule 5735 provides that if the investment adviser to the investment company issuing Managed Fund Shares is affiliated with a brokerdealer, such investment adviser shall erect a "fire wall" between the investment adviser and the brokerdealer with respect to access to information concerning the composition and/or changes to such investment company portfolio.7 In addition, paragraph (g) further requires that personnel who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material non-public information

<sup>6</sup> See Post-Effective Amendment No. 120 to Registration Statement on Form N–1A for the Trust, dated June 25, 2015 (File Nos. 333–174332 and 811–22559). The descriptions of the Fund and the Shares contained herein are based, in part, on information in the Registration Statement.

regarding the open-end fund's portfolio. Rule 5735(g) is similar to Nasdaq Rule 5705(b)(5)(A)(i); however, paragraph (g) in connection with the establishment of a "fire wall" between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds. Neither the Adviser nor the Sub-Adviser is a broker-dealer, although the Adviser is affiliated with the Distributor, a broker-dealer. The Sub-Adviser is not affiliated with a brokerdealer. The Adviser has implemented a fire wall with respect to its brokerdealer affiliate regarding access to information concerning the composition and/or changes to the portfolio. In addition, personnel of the Adviser who make decisions on the Fund's portfolio composition will be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio. In the event (a) the Adviser or the Sub-Adviser becomes, or becomes newly affiliated with, a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with another broker-dealer, it will implement a fire wall with respect to its relevant personnel and/or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the portfolio and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

First Trust SSI Strategic Convertible Securities ETF

The investment objective of the Fund will be to seek total return. To achieve its objective, the Fund will invest, under normal market conditions,<sup>8</sup> at least 80% of its net assets (including investment

<sup>&</sup>lt;sup>7</sup> An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the "Advisers Act"). As a result, the Adviser, the Sub-Adviser and their related personnel are subject to the provisions of Rule 204A-1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A-1 under the Advisers Act. In addition, Rule 206(4)-7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

<sup>8</sup> The term "under normal market conditions" as used herein includes, but is not limited to, the absence of adverse market, economic, political or other conditions, including extreme volatility or trading halts in the fixed income markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance. On a temporary basis, including for defensive purposes, during the initial invest-up period and during periods of high cash inflows or outflows, the Fund may depart from its principal investment strategies; for example, it may hold a higher than normal proportion of its assets in cash. During such periods, the Fund may not be able to achieve its investment objective. The Fund may adopt a defensive strategy when the Adviser believes securities in which the Fund normally invests have elevated risks due to political or economic factors and in other extraordinary circumstances.

borrowings) in the following convertible securities: <sup>9</sup> convertible notes, bonds and debentures; convertible preferred securities; mandatory convertible securities; <sup>10</sup> contingent convertible securities; <sup>11</sup> synthetic convertible securities; <sup>12</sup> corporate bonds and preferred securities with attached warrants; <sup>13</sup> and convertible Rule 144A securities <sup>14</sup> (collectively, "Convertible Securities"). <sup>15</sup>

Through its investment process, the Sub-Adviser will attempt to identify attractive Convertible Securities based on its positive view of the Underlying Security or its view of the company's potential for credit improvement. The Sub-Adviser will begin its investment process by evaluating a large universe of available Convertible Securities and

<sup>9</sup>Convertible securities are investment instruments that are normally convertible or exchangeable into equity securities (such equity securities are referred to as "Underlying Securities") and/or the cash equivalent thereof. These equity-linked instruments offer the potential for equity market participation with potential mitigated downside risk in periods of equity market declines.

<sup>10</sup> Mandatory convertible securities are distinguished as a subset of convertible securities because the conversion is not optional and the conversion price is based solely upon the market price of the underlying equity security. Mandatory convertible securities automatically convert on maturity.

11 Contingent convertible securities (which generally provide for conversion under certain circumstances) are distinguished as a subset of convertible securities. Similar to mandatory convertible securities (and unlike traditional convertible securities), some contingent convertible securities provide for mandatory conversion under certain circumstances. In addition, various contingent convertible securities may contain features that limit an investor's ability to convert the security unless certain conditions are met.

12 A synthetic convertible security will (i) consist of two or more distinct securities whose economic characteristics, when taken together, resemble those of traditional convertible securities (i.e., an income-producing security and the right to acquire an equity security through, for example, an option or a warrant) or (ii) be an exchangeable or equity-linked security issued by a broker-dealer, investment bank or other financial institution with proceeds going directly to the broker-dealer, investment bank or other financial institution, as applicable, that has economic characteristics similar to those of traditional convertible securities.

<sup>13</sup> Other than warrants that represent a component of a synthetic convertible security, the Fund's investments in warrants will be limited to such attached warrants, and such attached warrants will be exchange-listed.

<sup>14</sup> Under normal market conditions, convertible Rule 144A securities will have, at the time of original issuance, \$100 million or more principal amount outstanding to be considered eligible investments.

<sup>15</sup> The Adviser expects that, under normal market conditions, generally, for a Convertible Security to be considered as an eligible investment, after taking into account such an investment, at least 75% of the Fund's net assets that are invested in Convertible Securities will be comprised of Convertible Securities that will have, at the time of original issuance, \$200 million or more par amount outstanding.

screening for liquidity and convexity. Convexity is the ratio of upside move in the Convertible Security in conjunction with appreciation of the Underlying Security relative to the downside move in the Convertible Security in conjunction with depreciation of the Underlying Security. The screening process will rely on the Sub-Adviser's fundamental credit evaluation of the issuers. This credit analysis will allow the Sub-Adviser to attempt to identify the downside risk of the Convertible Security, assess the value of the embedded equity and understand the amount of participation expected with a change in the price of the Underlying Security. Once attractive Convertible Securities (i.e., Convertible Securities that are most highly ranked, based on a ranking system incorporating target characteristics) have been identified, the Sub-Adviser will use fundamental equity analysis to determine which of the attractive Convertible Securities it believes have a sound Underlying Security with potential for increase in value. In conjunction with its analysis, the Sub-Adviser will review the overall economic situation. In this regard, the Fund will be actively managed, whereby, the Sub-Adviser will assess the position of the economic cycle and the performance outlook for certain economic sectors. The Sub-Adviser will, at times, overweight or underweight different economic sectors, market capitalizations, and credit quality exposures relative to the available universe of Convertible Securities. The Sub-Adviser may also adjust the sensitivity of the portfolio to movements in the equity market and to interest rates based on the macroeconomic outlook. The Fund may manage the market exposure defensively during periods of market distress.

The Fund will invest in Convertible Securities of any credit quality, including unrated securities, and with effective or final maturities of any length. Convertible Securities may be issued by domestic or foreign entities.

The Fund will hold debt securities (including, in the aggregate, Convertible Securities and the debt securities described below) of at least 13 non-affiliated issuers.

#### Other Investments of the Fund

The Fund may invest up to 20% of its net assets in short-term debt securities and other short-term debt instruments (described below), as well as cash equivalents, or it may hold cash. The percentage of the Fund invested in such holdings will vary and will depend on several factors, including market conditions.

Short-term debt instruments are issued by issuers having a long-term debt rating of at least A by Standard & Poor's Ratings Services ("S&P Ratings"), Moody's Investors Service, Inc. ("Moody's") or Fitch Ratings ("Fitch") and have a maturity of one year or less. The Fund may invest in the following short-term debt instruments: (1) Fixed rate and floating rate U.S. government securities, including bills, notes and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. government agencies or instrumentalities; (2) certificates of deposit issued against funds deposited in a bank or savings and loan association; (3) bankers' acceptances, which are short-term credit instruments used to finance commercial transactions; (4) repurchase agreements,16 which involve purchases of debt securities; (5) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (6) commercial paper, which is short-term unsecured promissory notes; <sup>17</sup> and (7) corporate debt obligations.

The Fund may invest up to 20% of its net assets in exchange-traded notes ("ETNs").

The Fund may invest up to 20% of its net assets in exchange-listed equity securities (referred to collectively as "Equity Securities"). 

18 In addition to U.S. exchange-listed equity securities of domestic issuers, Equity Securities may include securities of foreign issuers that are listed on U.S. or foreign exchanges as well as investments in equity securities that are in the form of American Depositary Receipts ("ADRs") or Global Depositary Receipts ("GDRs", and together with ADRs, "Depositary Receipts"). 

19 Positive Securities of the securi

<sup>&</sup>lt;sup>16</sup> The Fund intends to enter into repurchase agreements only with financial institutions and dealers believed by the Adviser and/or the Sub-Adviser to present minimal credit risks in accordance with criteria approved by the Board of Trustees of the Trust ("Trust Board"). The Adviser and/or the Sub-Adviser will review and monitor the creditworthiness of such institutions. The Adviser and/or the Sub-Adviser will monitor the value of the collateral at the time the transaction is entered into and at all times during the term of the repurchase agreement.

<sup>&</sup>lt;sup>17</sup> The Fund may only invest in commercial paper rated A–1 or higher by S&P Ratings, Prime-1 or higher by Moody's or F1 or higher by Fitch.

<sup>&</sup>lt;sup>18</sup> The Fund may hold Equity Securities either through direct investment or upon conversion of a Convertible Security into its corresponding Underlying Security (referred to as a "Post-Conversion Underlying Security").

<sup>&</sup>lt;sup>19</sup> The Fund will not invest in any unsponsored Depositary Receipts. In addition, for the avoidance of doubt, the term "Equity Securities" may include Continued

The Fund may invest up to 20% of its net assets in exchange-listed equity index futures contracts, in exchangelisted and over-the-counter ("OTC") index credit default swaps, and in forward foreign currency exchange contracts. The use of futures contracts may allow the Fund to obtain net long or short exposures to selected equity indexes. Index credit default swaps may be used to gain exposure to a basket of credit risk by "selling protection" against default or other credit events, or to hedge a broad market credit risk by "buying protection." Forward foreign currency exchange contracts may be used to protect the value of the Fund's portfolio against uncertainty in the level of future currency exchange rates.20 The Fund's investments in derivative instruments will be consistent with the Fund's investment objective and the 1940 Act and will not be used to seek to achieve a multiple or inverse multiple of an index. The Fund will only enter into transactions in OTC index credit default swaps and forward foreign currency exchange contracts with counterparties that the Adviser and/or the Sub-Adviser reasonably believes are capable of performing under the applicable agreement.<sup>21</sup>

#### **Investment Restrictions**

The Fund may not invest 25% or more of the value of its total assets in securities of issuers in any one industry. This restriction does not apply to (a) obligations issued or guaranteed by the U.S. government, its agencies or instrumentalities or (b) securities of other investment companies.<sup>22</sup>

The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including Rule 144A securities deemed illiquid by the

Adviser and/or the Sub-Adviser.<sup>23</sup> The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.24

#### Creation and Redemption of Shares

The Fund will issue and redeem Shares on a continuous basis at net asset value ("NAV") <sup>25</sup> only in large blocks of Shares ("Creation Units") in transactions with authorized participants, generally including broker-dealers and large institutional investors ("Authorized Participants"). Creation Units generally will consist of 50,000 Shares, although this may change from time to time. Creation Units, however, are not expected to consist of less than 50,000 Shares. As described in the Registration Statement and consistent

with the Exemptive Relief, the Fund will issue and redeem Creation Units in exchange for an in-kind portfolio of instruments and/or cash in lieu of such instruments (the "Creation Basket"). In addition, if there is a difference between the NAV attributable to a Creation Unit and the market value of the Creation Basket exchanged for the Creation Unit, the party conveying instruments with the lower value will pay to the other an amount in cash equal to the difference (referred to as the "Cash Component").

Creations and redemptions must be made by or through an Authorized Participant that has executed an agreement that has been agreed to by the Distributor and BNY with respect to creations and redemptions of Creation Units. All standard orders to create Creation Units must be received by the transfer agent no later than the closing time of the regular trading session on the NYSE (ordinarily 4:00 p.m., Eastern Time) (the "Closing Time") in each case on the date such order is placed in order for the creation of Creation Units to be effected based on the NAV of Shares as next determined on such date after receipt of the order in proper form. Shares may be redeemed only in Creation Units at their NAV next determined after receipt not later than the Closing Time of a redemption request in proper form by the Fund through the transfer agent and only on a business day.

The Fund's custodian, through the National Securities Clearing Corporation, will make available on each business day, prior to the opening of business of the Exchange, the list of the names and quantities of the instruments comprising the Creation Basket, as well as the estimated Cash Component (if any), for that day. The published Creation Basket will apply until a new Creation Basket is announced on the following business day prior to commencement of trading in the Shares.

#### Net Asset Value

The Fund's NAV will be determined as of the close of regular trading on the NYSE on each day the NYSE is open for trading. If the NYSE closes early on a valuation day, the NAV will be determined as of that time. NAV per Share will be calculated for the Fund by taking the market price of the Fund's total assets, including interest or dividends accrued but not vet collected, less all liabilities, and dividing such amount by the total number of Shares outstanding. The result, rounded to the nearest cent, will be the NAV per Share. All valuations will be subject to review by the Trust Board or its delegate.

exchange-listed equity securities of business development companies ("BDCs").

 $<sup>^{20}</sup>$  The Fund may also enter into foreign currency transactions on a spot (*i.e.*, cash) basis.

<sup>&</sup>lt;sup>21</sup> The Fund will seek, where possible, to use counterparties, as applicable, whose financial status is such that the risk of default is reduced; however, the risk of losses resulting from default is still possible. The Adviser and/or the Sub-Adviser will evaluate the creditworthiness of counterparties on an ongoing basis. In addition to information provided by credit agencies, the Adviser's and/or Sub-Adviser's analysis will evaluate each approved counterparty using various methods of analysis and may consider the Adviser's and/or Sub-Adviser's past experience with the counterparty, its known disciplinary history and its share of market participation.

<sup>&</sup>lt;sup>22</sup> See Form N-1A, Item 9. The Commission has taken the position that a fund is concentrated if it invests more than 25% of the value of its total assets in any one industry. See, e.g., Investment Company Act Release No. 9011 (October 30, 1975), 40 FR 54241 (November 21, 1975).

<sup>&</sup>lt;sup>23</sup> In reaching liquidity decisions, the Adviser and the Sub-Adviser may consider the following factors: the frequency of trades and quotes for the security; the number of dealers wishing to purchase or sell the security and the number of other potential purchasers; dealer undertakings to make a market in the security; and the nature of the security and the nature of the marketplace in which it trades (e.g., the time needed to dispose of the security, the method of soliciting offers and the mechanics of transfer)

<sup>&</sup>lt;sup>24</sup> The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. See Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), footnote 34. See also Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding "Restricted Securities"); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N-1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. See Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a-7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990). 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act of 1933)

<sup>25</sup> The NAV of the Fund's Shares generally will be calculated once daily Monday through Friday as of the close of regular trading on the New York Stock Exchange ("NYSE"), generally 4:00 p.m., Eastern Time (the "NAV Calculation Time"). NAV per Share will be calculated by dividing the Fund's net assets by the number of Fund Shares outstanding. For more information regarding the valuation of Fund investments in calculating the Fund's NAV, see the Registration Statement.

The Fund's investments will be valued daily at market value or, in the absence of market value with respect to any investments, at fair value. Market value prices represent last sale or official closing prices from a national or foreign exchange (i.e., a regulated market) and will primarily be obtained from third party pricing services (each, a "Pricing Service"). Fair value prices represent any prices not considered market value prices and will either be obtained from a Pricing Service or determined by the pricing committee of the Adviser (the "Pricing Committee"),26 in accordance with valuation procedures (which may be revised from time to time) adopted by the Trust Board (the "Valuation Procedures"), and in accordance with provisions of the 1940 Act. The information summarized below is based on the Valuation Procedures as currently in effect; however, as noted above, the Valuation Procedures are amended from time to time and, therefore, such information is subject to change.

Certain securities, including in particular Convertible Securities, in which the Fund may invest will not be listed on any securities exchange or board of trade. Such securities will typically be bought and sold by institutional investors in individually negotiated private transactions that function in many respects like an OTC secondary market, although typically no formal market makers will exist. Certain securities, particularly debt securities, will have few or no trades, or trade infrequently, and information regarding a specific security may not be widely available or may be incomplete. Accordingly, determinations of the fair value of debt securities may be based on infrequent and dated information. Because there is less reliable, objective data available, elements of judgment may play a greater role in valuation of debt securities than for other types of securities.

The following investments will typically be fair valued using information provided by a Pricing Service or obtained from broker-dealer quotations: (a) Convertible Securities (including convertible notes, bonds and debentures; convertible preferred securities; mandatory convertible securities; contingent convertible securities; synthetic convertible securities; corporate bonds and preferred securities with attached

warrants; 27 and convertible Rule 144A securities); 28 (b) except as provided below, short-term U.S. government securities, commercial paper, bankers' acceptances and short-term corporate debt obligations, all as set forth under "Other Investments of the Fund" (collectively, "Short-Term Debt Instruments"); and (c) OTC index credit default swaps. Debt instruments may be valued at evaluated bid prices, as provided by Pricing Services. Pricing Services typically value non-exchangetraded instruments utilizing a range of market-based inputs and assumptions, including readily available market quotations obtained from broker-dealers making markets in such instruments, cash flows, and transactions for comparable instruments. In pricing certain instruments, the Pricing Services may consider information about an instrument's issuer or market activity provided by the Adviser or the Sub-Adviser.

Short-Term Debt Instruments having a remaining maturity of 60 days or less when purchased will typically be valued at cost adjusted for amortization of premiums and accretion of discounts, provided the Pricing Committee has determined that the use of amortized cost is an appropriate reflection of fair value given market and issuer-specific conditions existing at the time of the determination.

Repurchase agreements will typically be fair valued as follows: Overnight repurchase agreements will be fair valued at cost. Term repurchase agreements (*i.e.*, those whose maturity exceeds seven days) will be fair valued at the average of the bid quotations obtained daily from at least two recognized dealers.

Common stocks and other equity securities (including Depositary Receipts, BDCs, Post-Conversion Underlying Securities, and other Equity Securities), as well as ETNs, listed on any exchange other than the Exchange and the London Stock Exchange Alternative Investment Market ("AIM") will typically be valued at the last sale price on the exchange on which they are principally traded on the business day as of which such value is being determined. Such equity securities and ETNs listed on the Exchange or the AIM

will typically be valued at the official closing price on the business day as of which such value is being determined. If there has been no sale on such day, or no official closing price in the case of securities traded on the Exchange or the AIM, such equity securities and ETNs will typically be valued using fair value pricing. Such equity securities and ETNs traded on more than one securities exchange will be valued at the last sale price or official closing price, as applicable, on the business day as of which such value is being determined at the close of the exchange representing the principal market for such securities.

Exchange-Listed Convertible Securities, exchange-listed equity index futures contracts and exchange-listed index credit default swaps will typically be valued at the closing price in the market where such instruments are principally traded. If no official closing price is available, such instruments will be fair valued at the mean of their most recent bid and asked price on the exchange on which they are principally traded, if available, and otherwise at their closing bid price.

Forward foreign currency exchange contracts will typically be fair valued at the current day's interpolated foreign exchange rate, as calculated using the current day's spot rate, and the thirty, sixty, ninety and one-hundred-eighty day forward rates provided by a Pricing Service or by certain independent dealers in such contracts.

Because foreign exchanges may be open on different days than the days during which an investor may purchase or sell Shares, the value of the Fund's assets may change on days when investors are not able to purchase or sell Shares. Assets denominated in foreign currencies will be translated into U.S. dollars at the exchange rate of such currencies against the U.S. dollar as provided by a Pricing Service. The value of assets denominated in foreign currencies will be converted into U.S. dollars at the exchange rates in effect at the time of valuation.

Valuing the Fund's assets using fair value pricing can result in using prices for those assets (particularly assets that trade in foreign markets) that may differ from current market valuations.

#### Availability of Information

The Fund's Web site (www.ftportfolios.com), which will be publicly available prior to the public offering of Shares, will include a form of the prospectus for the Fund that may be downloaded. The Web site will include the Shares' ticker, CUSIP and exchange information along with additional quantitative information

<sup>&</sup>lt;sup>26</sup> The Pricing Committee will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the Fund's portfolio.

<sup>&</sup>lt;sup>27</sup> Although the attached warrants will be exchange-listed, for purposes of valuation, these Convertible Securities will typically be treated as single non-exchange-listed instruments.

<sup>&</sup>lt;sup>28</sup>Convertible Securities are generally not expected to be exchange-listed. However, to the extent the Fund invests in any Convertible Securities that are exchange-listed (referred to as "Exchange-Listed Convertible Securities"), they will be valued as provided below.

updated on a daily basis, including, for the Fund: (1) Daily trading volume, the prior business day's reported NAV and closing price, mid-point of the bid/ask spread at the time of calculation of such NAV (the "Bid/Ask Price"),29 and a calculation of the premium and discount of the Bid/Ask Price against the NAV; and (2) data in chart format displaying the frequency distribution of discounts and premiums of the daily Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. On each business day, before commencement of trading in Shares in the Regular Market Session 30 on the Exchange, the Fund will disclose on its Web site the identities and quantities of the portfolio of securities, and other assets (the "Disclosed Portfolio" as defined in Nasdag Rule 5735(c)(2)) held by the Fund that will form the basis for the Fund's calculation of NAV at the end of the business day.31 The Fund's disclosure of derivative positions in the Disclosed Portfolio will include information that market participants can use to value these positions intraday. On a daily basis, the Fund will disclose on the Fund's Web site the following information regarding each portfolio holding, as applicable to the type of holding: ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding, such as the type of swap), the identity of the security or other asset or instrument underlying the holding, if any; quantity held (as measured by, for example, par value, notional value or number of shares, contracts or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and percentage weighting of the holding in the Fund's portfolio. The Web site information will be publicly available at no charge.

In addition, for the Fund, an estimated value, defined in Rule 5735(c)(3) as the "Intraday Indicative

Value," that reflects an estimated intraday value of the Fund's Disclosed Portfolio, will be disseminated. Moreover, the Intraday Indicative Value, available on the NASĎAQ OMX Information LLC proprietary index data service, 32 will be based upon the current value for the components of the Disclosed Portfolio and will be updated and widely disseminated by one or more major market data vendors and broadly displayed at least every 15 seconds during the Regular Market Session. The Intraday Indicative Value will be based on quotes and closing prices from the securities' local market and may not reflect events that occur subsequent to the local market's close. Premiums and discounts between the Intraday Indicative Value and the market price may occur. This should not be viewed as a "real time" update of the NAV per Share of the Fund, which is calculated only once a day.

The dissemination of the Intraday Indicative Value, together with the Disclosed Portfolio, will allow investors to determine the value of the underlying portfolio of the Fund on a daily basis and will provide a close estimate of that value throughout the trading day.

Investors will also be able to obtain the Fund's Statement of Additional Information ("SAI"), the Fund's annual and semi-annual reports (together, "Shareholder Reports"), and its Form N-CSR and Form N-SAR, filed twice a year. The Fund's SAI and Shareholder Reports will be available free upon request from the Fund, and those documents and the Form N-CSR and Form N-SAR may be viewed on-screen or downloaded from the Commission's Web site at www.sec.gov. Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available via Nasdaq proprietary quote and trade services, as well as in accordance with the Unlisted Trading Privileges and the Consolidated Tape Association ("CTA") plans for the

Shares. Quotation and last sale information for U.S. exchange-listed equity securities will be available from the exchanges on which they are traded as well as in accordance with any applicable CTA plans. Pricing information for Exchange-Listed Convertible Securities; ETNs; Depositary Receipts, BDCs, Post-Conversion Underlying Securities, and other Equity Securities; exchange-listed equity index futures contracts; and exchange-listed index credit default swaps will be available from the applicable listing exchange and from major market data vendors. Pricing information for OTC Convertible Securities (including convertible notes, bonds and debentures; convertible preferred securities; mandatory convertible securities; contingent convertible securities; synthetic convertible securities; corporate bonds and preferred securities with attached warrants; 33 and convertible Rule 144A securities); Short-Term Debt Instruments (including short-term U.S. government securities, commercial paper, bankers' acceptances and shortterm corporate debt obligations, all as set forth under "Other Investments of the Fund"); repurchase agreements; OTC index credit default swaps; and forward foreign currency exchange contracts will be available from major broker-dealer firms and/or major market data vendors and/or Pricing Services.

Additional information regarding the Fund and the Shares, including investment strategies, risks, creation and redemption procedures, fees, Fund holdings disclosure policies, distributions and taxes will be included in the Registration Statement.

#### Initial and Continued Listing

The Shares will be subject to Rule 5735, which sets forth the initial and continued listing criteria applicable to Managed Fund Shares. The Exchange represents that, for initial and/or continued listing, the Fund must be in compliance with Rule 10A–3 <sup>34</sup> under the Act. A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange. The Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made

<sup>&</sup>lt;sup>29</sup> The Bid/Ask Price of the Fund will be determined using the mid-point of the highest bid and the lowest offer on the Exchange as of the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund and its service providers.

<sup>&</sup>lt;sup>30</sup> See Nasdaq Rule 4120(b)(4) (describing the three trading sessions on the Exchange: (1) Pre-Market Session from 4 a.m. to 9:30 a.m., Eastern Time; (2) Regular Market Session from 9:30 a.m. to 4 p.m. or 4:15 p.m., Eastern Time; and (3) Post-Market Session from 4 p.m. or 4:15 p.m. to 8 p.m., Eastern Time).

<sup>&</sup>lt;sup>31</sup>Under accounting procedures to be followed by the Fund, trades made on the prior business day ("T") will be booked and reflected in NAV on the current business day ("T+1"). Accordingly, the Fund will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

<sup>&</sup>lt;sup>32</sup> Currently, the NASDAQ OMX Global Index Data Service ("GIDS") is the NASDAQ OMX global index data feed service, offering real-time updates, daily summary messages, and access to widely followed indexes and Intraday Indicative Values for ETFs. GIDS provides investment professionals with the daily information needed to track or trade NASDAQ OMX indexes, listed ETFs, or third-party partner indexes and ETFs.

<sup>&</sup>lt;sup>33</sup> Although the attached warrants will be exchange-listed, for purposes of obtaining pricing information, these Convertible Securities will typically be treated as single non-exchange-listed instruments.

<sup>&</sup>lt;sup>34</sup> See 17 CFR 240.10A–3.

available to all market participants at the same time.

#### Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund. Nasdaq will halt trading in the Shares under the conditions specified in Nasdaq Rules 4120 and 4121, including the trading pauses under Nasdaq Rules 4120(a)(11) and (12). Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the securities and/or the other assets constituting the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 5735(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted.

#### **Trading Rules**

Nasdaq deems the Shares to be equity securities, thus rendering trading in the Shares subject to Nasdaq's existing rules governing the trading of equity securities. Nasdaq will allow trading in the Shares from 4:00 a.m. until 8:00 p.m., Eastern Time. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in Nasdaq Rule 5735(b)(3), the minimum price variation for quoting and entry of orders in Managed Fund Shares traded on the Exchange is \$0.01.

#### Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and also the Financial Industry Regulatory Authority ("FINRA") on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.<sup>35</sup> The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns,

which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and the exchangetraded securities and instruments held by the Fund (including Exchange-Listed Convertible Securities; ETNs; Depositary Receipts, BDCs, Post-Conversion Underlying Securities, and other Equity Securities; exchange-listed equity index futures contracts; and exchange-listed index credit default swaps) with other markets and other entities that are members of the Intermarket Surveillance Group ("ISG"),36 and FINRA may obtain trading information regarding trading in the Shares and the exchange-traded securities and instruments held by the Fund from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and the exchange-traded securities and instruments held by the Fund from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement. Moreover, FINRA, on behalf of the Exchange, will be able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's Trade Reporting and Compliance Engine ("TRACE").

At least 90% of the Fund's net assets that are invested in Exchange-Listed Convertible Securities; ETNs; Depositary Receipts, BDCs, Post-Conversion Underlying Securities, and other Equity Securities; exchange-listed equity index futures contracts; and exchange-listed index credit default swaps (in the aggregate) will be invested in investments that trade in markets that are members of ISG or are parties to a comprehensive surveillance sharing agreement with the Exchange. Further, at least 90% of the Underlying Securities corresponding to the preconversion Convertible Securities held by the Fund (measured by par value) will trade in markets that are members of ISG or are parties to a comprehensive

surveillance sharing agreement with the Exchange.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

#### Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (1) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (2) Nasdaq Rule 2111A, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (3) how information regarding the Intraday Indicative Value and the Disclosed Portfolio is disseminated; (4) the risks involved in trading the Shares during the Pre-Market and Post-Market Sessions when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (5) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (6) trading information. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the

Additionally, the Information Circular will reference that the Fund is subject to various fees and expenses described in the Registration Statement. The Information Circular will also disclose the trading hours of the Shares of the Fund and the applicable NAV Calculation Time for the Shares. The Information Circular will disclose that information about the Shares of the Fund will be publicly available on the Fund's Web site.

#### 2. Statutory Basis

Nasdaq believes that the proposal is consistent with Section 6(b) of the Act in general and Section 6(b)(5) of the Act in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

<sup>&</sup>lt;sup>35</sup> FINRA surveils trading on the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

<sup>&</sup>lt;sup>36</sup> For a list of the current members of ISG, see www.isgportal.org. The Exchange notes that not all components of the Disclosed Portfolio may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Nasdaq Rule 5735. The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and also FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.

Neither the Adviser nor the Sub-Adviser is a broker-dealer, although the Adviser is affiliated with the Distributor, a broker-dealer. The Sub-Adviser is not affiliated with a brokerdealer. The Adviser has implemented a fire wall with respect to its brokerdealer affiliate regarding access to information concerning the composition and/or changes to the portfolio. In addition, paragraph (g) of Nasdaq Rule 5735 further requires that personnel of the Adviser who make decisions on the open-end fund's portfolio composition must be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the open-end fund's portfolio.

FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and the exchangetraded securities and instruments held by the Fund (including Exchange-Listed Convertible Securities; ETNs; Depositary Receipts, BDCs, Post-Conversion Underlying Securities, and other Equity Securities; exchange-listed equity index futures contracts; and exchange-listed index credit default swaps) with other markets and other entities that are members of ISG, and FINRA may obtain trading information regarding trading in the Shares and the exchange-traded securities and instruments held by the Fund from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and the exchange-traded securities and instruments held by the Fund from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement. Moreover, FINRA, on behalf of the Exchange, will be able to access, as needed, trade information for certain fixed income securities held by the Fund reported to FINRA's TRACE.

At least 90% of the Fund's net assets that are invested in Exchange-Listed Convertible Securities; ETNs; Depositary Receipts, BDCs, Post-Conversion Underlying Securities, and

other Equity Securities; exchange-listed equity index futures contracts; and exchange-listed index credit default swaps (in the aggregate) will be invested in investments that trade in markets that are members of ISG or are parties to a comprehensive surveillance sharing agreement with the Exchange. Further, at least 90% of the Underlying Securities corresponding to the preconversion Convertible Securities held by the Fund (measured by par value) will trade in markets that are members of ISG or are parties to a comprehensive surveillance sharing agreement with the Exchange.

The investment objective of the Fund will be to seek total return. To achieve its objective, the Fund will invest, under normal market conditions, at least 80% of its net assets (including investment borrowings) in a portfolio of Convertible Securities. The Fund may invest up to 20% of its net assets in exchange-listed equity index futures contracts, in exchange-listed and OTC index credit default swaps, and in forward foreign currency exchange contracts. The Fund's investments in derivative instruments will be consistent with the Fund's investment objective and the 1940 Act and will not be used to seek to achieve a multiple or inverse multiple of an index. The Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), including Rule 144A securities deemed illiquid by the Adviser and/or the Sub-Adviser. The Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. In addition, a large amount of information will be publicly available regarding the Fund and the Shares, thereby promoting market transparency. Moreover, the

Intraday Indicative Value, available on the NASDAO OMX Information LLC proprietary index data service, will be widely disseminated by one or more major market data vendors and broadly displayed at least every 15 seconds during the Regular Market Session. On each business day, before commencement of trading in Shares in the Regular Market Session on the Exchange, the Fund will disclose on its Web site the Disclosed Portfolio that will form the basis for the Fund's calculation of NAV at the end of the business day. Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services, and quotation and last sale information for the Shares will be available via Nasdaq proprietary quote and trade services, as well as in accordance with the Unlisted Trading Privileges and the CTA plans for the Shares. Quotation and last sale information for U.S. exchange-listed equity securities will be available from the exchanges on which they are traded as well as in accordance with any applicable CTA plans. Pricing information for Exchange-Listed Convertible Securities; ETNs; Depositary Receipts, BDCs, Post-Conversion Underlying Securities, and other Equity Securities; exchange-listed equity index futures contracts; and exchange-listed index credit default swaps will be available from the applicable listing exchange and from major market data vendors. Pricing information for OTC Convertible Securities (including convertible notes, bonds and debentures; convertible preferred securities; mandatory convertible securities; contingent convertible securities; synthetic convertible securities; corporate bonds and preferred securities with attached warrants; and convertible Rule 144A securities); Short-Term Debt Instruments (including short-term U.S. government securities, commercial paper, bankers' acceptances and shortterm corporate debt obligations, all as set forth under "Other Investments of the Fund"); repurchase agreements; OTC index credit default swaps; and forward foreign currency exchange contracts will be available from major broker-dealer firms and/or major market data vendors and/or Pricing Services.

The Fund's Web site will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information. Trading in Shares of the Fund will be halted under the

conditions specified in Nasdaq Rules 4120 and 4121 or because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable, and trading in the Shares will be subject to Nasdaq Rule 5735(d)(2)(D), which sets forth circumstances under which Shares of the Fund may be halted. In addition, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

The Fund's investments will be valued daily at market value or, in the absence of market value with respect to any investments, at fair value. Market value prices represent last sale or official closing prices from a national or foreign exchange (i.e., a regulated market) and will primarily be obtained from Pricing Services. Fair value prices represent any prices not considered market value prices and will either be obtained from a Pricing Service or determined by the Pricing Committee, in accordance with the Valuation Procedures and in accordance with provisions of the 1940 Act. The Pricing Committee will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the Fund's portfolio.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of activelymanaged exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and the exchangetraded securities and instruments held by the Fund (including Exchange-Listed Convertible Securities; ETNs; Depositary Receipts, BDCs, Post-Conversion Underlying Securities, and other Equity Securities; exchange-listed equity index futures contracts; and exchange-listed index credit default swaps) with other markets and other entities that are members of ISG, and FINRA may obtain trading information regarding trading in the Shares and the exchange-traded securities and instruments held by the Fund from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and in the exchange-traded securities and instruments held by the Fund from markets and other entities that are

members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement. Furthermore, as noted above, investors will have ready access to information regarding the Fund's holdings, the Intraday Indicative Value, the Disclosed Portfolio, and quotation and last sale information for the Shares.

For the above reasons, Nasdaq believes the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change will facilitate the listing and trading of an additional type of actively-managed exchange-traded fund that will enhance competition among market participants, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

#### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the Federal Register or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will: (a) By order approve or disapprove such proposed rule change; or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

#### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

• Use the Commission's Internet comment form (http://www.sec.gov/rules/sro.shtml); or

• Send an email to *rule-comments@* sec.gov. Please include File Number

SR-NASDAQ-2015-075 on the subject line.

#### Paper Comments

• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, Station Place, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR-NASDAQ-2015-075. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site http://www.sec.gov/ rules/sro.shtml. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of Nasdaq. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NASDAQ-2015-075 and should be submitted on or before August 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.  $^{37}$ 

#### Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-17658 Filed 7-17-15; 8:45 am]

BILLING CODE 8011-01-P

<sup>37 17</sup> CFR 200.30-3(a)(12).

### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75448; File No. SR–MIAX–2015–46]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rules 307 and 309 To Extend the SPY Pilot Program

July 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b–4 thereunder,² notice is hereby given that on July 10, 2015, Miami International Securities Exchange LLC ("MIAX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rules 307 and 309 to extend the pilot program that eliminates the position and exercise limits for physically-settled options on the SPDR S&P 500 ETF Trust ("SPY Pilot Program").

The text of the proposed rule change is available on the Exchange's Web site at <a href="http://www.miaxoptions.com/filter/wotitle/rule\_filing">http://www.miaxoptions.com/filter/wotitle/rule\_filing</a>, at MIAX's principal office, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The Exchange proposes to amend Exchange Rule 307, Commentary .01, Position Limits, and Exchange Rule 309, Commentary .01, Exercise limits, to extend the duration of the SPY Pilot Program through July 12, 2016. There are no substantive changes being proposed to the SPY Pilot Program. In proposing to extend the SPY Pilot Program, the Exchange affirms its consideration of several factors that support the proposal to establish the SPY Pilot Program, which include: (1) The liquidity of the option and the underlying security; (2) the market capitalization of the underlying security and the securities that make up the S&P 500 Index; (3) options reporting requirements; and (4) financial requirements imposed by MIAX and the Commission.

The Exchange notes that it is not aware of any problems created by the current SPY Pilot Program and does not foresee any problems with the proposed extension. The Exchange formally submitted a Pilot Report for the SPY Pilot Program as part of this filing. In addition, the Exchange represents that if it chooses to extend or seek permanent approval of the SPY Pilot Program, the Exchange will submit another Pilot Report at least thirty (30) days prior to the expiration of the extended SPY Pilot Program time period which would cover the period between reports. The Pilot Report will compare the impact of the pilot program, if any, on the volumes of SPY options and the volatility in the price of the underlying SPY contract, particularly at expiration. The Pilot Report also will detail the size and different types of strategies employed with respect to positions established in SPY options; note whether any problems, in the underlying SPY ETF or otherwise, arose as a result of the nolimit approach; and include any other information that may be useful in evaluating the effectiveness of the pilot program. In preparing the Pilot Report, the Exchange will utilize various data elements such as volume and open interest. In addition the Exchange would make available to Commission staff data elements relating to the effectiveness of the SPY Pilot Program.

The Exchange purposes [sic] to extend the SPY Pilot Program in order for the Exchange and the Commission to have additional time to evaluate the Pilot and its effect on the market and to determine whether to seek permanent approval.

Prior to the expiration of the SPY Pilot Program and based upon the findings of the Pilot Report, the Exchange will be able to either extend the SPY Pilot Program, adopt the SPY Pilot Program on a permanent basis, or terminate the SPY Pilot Program. If the SPY Pilot Program is not extended or adopted on a permanent basis by the expiration of the Extended Pilot, the position limits for SPY would revert to limits in effect prior to the commencement of the SPY Pilot Program.

#### 2. Statutory Basis

MIAX believes that its proposed rule change is consistent with Section 6(b) of the Act 3 in general, and furthers the objectives of Section 6(b)(5) of the Act 4 in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

Specifically, the Exchange believes that extending the SPY Pilot Program promotes just and equitable principles of trade by permitting market participants, including market makers, institutional investors and retail investors, to establish greater positions when pursuing their investment goals and needs. The Exchange also believes that economically equivalent products

should be treated in an equivalent

manner so as to avoid regulatory

arbitrage, especially with respect to position limits. Treating SPY and SPX options differently by virtue of imposing different position limits is inconsistent with the notion of promoting just and equitable principles of trade and removing impediments to perfect the mechanisms of a free and open market. At the same time, the Exchange believes that the elimination of position limits for SPY options would not increase market volatility or facilitate the ability to manipulate the market.

#### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any aspect of competition,

<sup>&</sup>lt;sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>&</sup>lt;sup>2</sup> 17 CFR 240.19b-4.

<sup>3 15</sup> U.S.C. 78f(b).

<sup>4 15</sup> U.S.C. 78f(b)(5).

whether between the Exchange and its competitors, or among market participants. Instead, the proposed rule change is designed to allow the SPY Pilot Program to continue as the Exchange believes other competing options exchanges will also extend the SPY Pilot Program for another year.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

#### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.<sup>5</sup>

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act 6 normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii) 7 permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will allow the SPY Pilot Program to continue without interruption. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.8

At any time within 60 days of the filing of the proposed rule change, the

Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

#### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@ sec.gov*. Please include File Number SR–MIAX–2015–46 on the subject line.

#### Paper Comments

• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-MIAX-2015-46. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make

available publicly. All submissions should refer to File Number SR–MIAX–2015–46, and should be submitted on or before August 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>9</sup>

#### Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-17659 Filed 7-17-15; 8:45 am]

BILLING CODE 8011-01-P

### SECURITIES AND EXCHANGE COMMISSION

[Release No. IA-4140/803-00219]

### Crescent Capital Group, LP; Notice of Application

July 14, 2015.

**AGENCY:** Securities and Exchange Commission ("Commission").

**ACTION:** Notice of application for an exemptive order under Section 206A of the Investment Advisers Act of 1940 (the "Advisers Act") and Rule 206(4)–5(e) thereunder.

**APPLICANT:** Crescent Capital Group, LP ("Applicant").

#### **RELEVANT ADVISERS ACT SECTIONS:**

Exemption requested under Section 206A of the Advisers Act and Rule 206(4)–5(e) thereunder from Rule 206(4)–5(a)(1) under the Advisers Act.

summary of application: Applicant requests that the Commission issue an order under Section 206A of the Advisers Act and Rule 206(4)–5(e) thereunder exempting Applicant from Rule 206(4)–5(a)(1) under the Advisers Act to permit Applicant to receive compensation from a government entity client for investment advisory services provided to the government entity within the two-year period following a contribution by a covered associate of Applicant to an official of the government entity.

**FILING DATES:** The application was filed on October 31, 2013, and an amended and restated application was filed on March 12, 2015.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving Applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on August 10, 2015, and should be accompanied by proof of

<sup>&</sup>lt;sup>5</sup>17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

<sup>6 17</sup> CFR 240.19b-4(f)(6).

<sup>717</sup> CFR 240.19b-4(f)(6)(iii).

<sup>&</sup>lt;sup>8</sup>For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

<sup>9 17</sup> CFR 200.30-3(a)(12).

service on Applicant, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Advisers Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Commission's Secretary.

ADDRESSES: Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicant, Crescent Capital Group, LP, c/o George Hawley, Esq., 1100 Santa Monica Boulevard, Suite 2000, Los Angeles, CA 90025.

FOR FURTHER INFORMATION CONTACT: Kyle R. Ahlgren, Senior Counsel, or Holly L. Hunter-Ceci, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained via the Commission's Web site either at <a href="http://www.sec.gov/rules/iareleases.shtml">http://www.sec.gov/rules/iareleases.shtml</a> or by searching for the file number, or for an applicant using the Company name box, at <a href="http://www.sec.gov/search/search.htm">http://www.sec.gov/search/search.htm</a>, or by calling (202) 551–8090.

#### **Applicant's Representations**

- 1. Applicant is registered with the Commission as an investment adviser under the Advisers Act. Applicant provides investment advisory services to two private equity funds formed in 2006 and 2008, TCW/Crescent Mezzanine Partners IV, L.P. ("Fund IV") and TCW/Crescent Mezzanine Partners V, L.P. ("Fund V", and together with Fund IV, the "Funds"), as well as additional funds. The Funds are 'covered investment pools" as defined in Rule 206(4)-5(f)(3)(ii) under the Advisers Act that make long-term investments in private companies and other illiquid assets.
- 2. Mr. Jean Marc Chapus (the "Contributor") is a managing partner of Applicant. The Contributor is, and was at all relevant times, a "covered associate" of Applicant as that term is defined in Rule 206(4)–5(f)(2). The Contributor frequently has been solicited for, and has made, political contributions in the past.
- 3. The Los Angeles City Employees' Retirement System (the "Plan") falls within the definition of a "government entity" as that term is defined in Rule 206(4)–5(f)(5)(iii). The Plan invested in the Funds in 2006 and 2008, (for Fund IV and Fund V, respectively) and each Fund has been closed to new investors

- since that time. Under the terms of the governing documents of the Funds, investors, including the Plan, are not permitted to withdraw their investments, except under extraordinary circumstances that are beyond the control of either Applicant or the Plan, for a period of ten years following the date of the investment (2016 or 2018 for Fund IV and Fund V, respectively). Applicant's fees were established at the inception of the Funds and are not subject to renegotiation during the term of the investment.
- 4. In June 2011, an individual known to the Contributor, but unrelated to Applicant, contacted him directly and requested a contribution to the campaign of Mr. Austin Beutner (the "Recipient"), a candidate for the office of Mayor of Los Angeles (the "Office"). The Office is entitled to appoint members of the Plan's Board of Administration who can influence the selection of investment advisers for the Plan and other related public pension plans. On June 10, 2011, the Contributor made a contribution of \$1,000 (the "Contribution") to the Austin Beutner for Los Angeles Mayor 2013 Exploratory Committee (the "Committee"). At the time of the Contribution, each of the Committee and the Recipient was an "official" for purposes of Rule 206(4)-5(f)(6). The Recipient withdrew from the campaign prior to the election.
- 5. At the time of the Contribution, there was no discussion of the Office's appointment powers, influence or responsibilities involving any investment of public pension funds. Neither Applicant nor the Contributor sought to interfere with the Plan's meritbased selection process for advisory services, nor did they seek to negotiate higher fees or greater ancillary benefits than would be achieved in an arm's length transactions, nor could they have, as the selections pre-dated the Contribution. Applicant had an existing relationship with the Plan at the time of the Contribution, but did not engage in any new sales efforts involving limited partnership interests in the Funds, including any efforts designed to retain the investments in the Funds or to renegotiate its fees.
- 6. Applicant first became aware of the Contribution one month following the date it was made when, in July 2011, as a result of a quarterly survey of political contributions conducted by Applicant's compliance department pursuant to Applicant's contribution policies and procedures, the Contribution was self-reported by the Contributor. Upon learning of the Contribution, Applicant's chief compliance officer, with the cooperation of the Contributor,

- promptly contacted the Committee, which returned the Contribution shortly thereafter. At the same time, Applicant created an escrow account to custody advisory fees for the Funds that were attributable to the Plan. The fees that Applicant otherwise would have earned during the two-year period following the Contribution (the "Time Out Period") remain in the escrow account.
- 7. At the time of the Contribution, Applicant had developed written policies and procedures to assure compliance with Rule 206(4)–5. The policies and procedures included a requirement for pre-clearance of all political contributions and provided for quarterly surveys of all covered associates. Such policies and procedures were designed, among other things, to assure that any unreported political contributions were detected by Applicant's compliance department in a timely fashion.
- 8. Åt the time of the Contribution, communication from the Committee, as well as the Committee's Web site and other published information, referred consistently to its "exploratory" nature.¹ While the Contributor had received compliance training, he did not consider whether Rule 206(4)–5 and Applicant's pre-clearance requirement would have applied to contributions made to exploratory committees. The Contributor therefore did not pre-clear the Contribution with Applicant as required under its policies.
- 9. Subsequent to the Contribution, Applicant has enhanced its training program by stressing the importance of its pre-clearance requirement and has highlighted the fact that contributions to exploratory and other political committees are subject to its preclearance requirement, among other things.

#### **Applicant's Legal Analysis**

1. Rule 206(4)–5(a)(1) under the Advisers Act prohibits a registered investment adviser from providing investment advisory services for compensation to a government entity within two years after a contribution to an official of the government entity is made by the investment adviser or any covered associate of the investment adviser. The Plan is a "government entity," as defined in Rule 206(4)–5(f)(5), the Contributor is a "covered associate" as defined in Rule 206(4)–5(f)(2), and each of the Committee and the Recipient is an "official" as defined

<sup>&</sup>lt;sup>1</sup> The Committee had in fact filed as a campaign committee with the local election commission. Under Rule 206(4)–5(f)(6), the term "official" includes election committees.

in Rule 206(4)–5(f)(6). Rule 206(4)–5(c) provides that when a government entity invests in a covered investment pool, the investment adviser to that covered investment pool is treated as providing advisory services directly to the government entity. The Funds are "covered investment" pools as defined in Rule 206(4)–5(f)(3)(ii).

2. Section 206A of the Advisers Act grants the Commission the authority to "conditionally or unconditionally exempt any person or transaction . . . from any provision or provisions of [the Advisers Act] or of any rule or regulation thereunder, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of [the Advisers Act]."

3. Rule 206(4)–5(e) provides that the Commission may exempt an investment adviser from the prohibition under Rule 206(4)–5(a)(1) upon consideration of the factors listed below, among others:

(1) Whether the exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Advisers Act;

(2) Whether the investment adviser: (i) Before the contribution resulting in the prohibition was made, adopted and implemented policies and procedures reasonably designed to prevent violations of the rule; and (ii) prior to or at the time the contribution which resulted in such prohibition was made, had no actual knowledge of the contribution; and (iii) after learning of the contribution: (A) Has taken all available steps to cause the contributor involved in making the contribution which resulted in such prohibition to obtain a return of the contribution; and (B) has taken such other remedial or preventive measures as may be appropriate under the circumstances;

(3) Whether, at the time of the contribution, the contributor was a covered associate or otherwise an employee of the investment adviser, or was seeking such employment;

(4) The timing and amount of the contribution which resulted in the prohibition;

(5) The nature of the election (e.g., federal, state or local); and

- (6) The contributor's apparent intent or motive in making the contribution which resulted in the prohibition, as evidenced by the facts and circumstances surrounding such contribution.
- 4. Applicant requests an order pursuant to Section 206A and Rule

206(4)–5(e), exempting it from the twoyear prohibition on compensation imposed by Rule 206(4)–5(a)(1) with respect to investment advisory services provided to the Funds within the twoyear period following the Contribution.

5. Applicant submits that the exemption is necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicant further submits that the other factors set forth in Rule 206(4)–5 similarly weigh in favor of granting an exemption to Applicant to avoid consequences disproportionate to the violation.

6. Applicant states that the Plan first determined to invest in the Funds before the Contribution was made, and established and maintained its relationships with Applicant on an arm's length basis free from any improper influence as a result of the Contribution. Applicant notes that: (i) The Plan's most recent investment decision was made in 2008, prior to the Contribution, at the time of its last investment commitment in Fund V; and (ii) due to the committed nature of the Plan's investment in the Funds, the Plan had no investment decision to consider at the time of the Contribution.

7. Applicant states that it had developed policies and procedures to assure compliance with Rule 206(4)–5, which included a requirement for preclearance of all political contributions and provided for quarterly surveys of all covered associates, and that such quarterly survey prompted the Contributor to report the Contribution. Applicant further states that training was provided to Applicant's employees, including the Contributor, that addressed Rule 206(4)–5 and Applicant's policies and procedures.

8. Applicant states that at no time did any employees of Applicant, other than the Contributor, have any knowledge that the Contribution had been made prior to its disclosure by the Contributor in July 2011.

9. Applicant states that once the Contribution was discovered, Applicant began to gather additional facts about the Contribution and the Committee, and fees attributable to the Plan's investment in the Funds were placed in escrow. Applicant further states that after learning of the Contribution, Applicant took steps to limit the Contributor's contact with any representative of the Plan or related plans for the duration of the Time Out Period, and that the Contributor had no contact with any representative of the Plan or related plans during the Time Out Period.

- 10. Applicant states that the Contribution was made solely for the purpose of participating in the local election process, and was not intended to improperly influence any decision by the Plan. Applicant notes that the Contributor resides in the community in which the Recipient was running for office and that the Contributor was entitled to vote in the election. Applicant further states that the Contributor has a history of making political contributions to candidates for elected office.
- 11. Applicant states that Applicant had an existing relationship with the Plan at the time of the Contribution, but did not engage in any new sales efforts involving limited partnership interests in the Funds, including any efforts designed to retain the investments in the Funds or to renegotiate its fees.
- 12. Applicant contends that imposing a limitation on the receipt of advisory compensation associated with the Plan's investment in the Funds would result in a disproportionate consequence to Applicant that is not necessary to achieve the intended purposes of Rule 206(4)–5. Applicant states that neither Applicant nor the Contributor sought to interfere with the Plan's merit-based selection process for advisory services, nor did they seek to negotiate higher fees or greater ancillary benefits than would be achieved in an arm's length transactions, nor could they have, as the selections pre-dated the Contribution. Applicant further states that there was no violation of Applicant's fiduciary duty to deal fairly or disclose material conflicts of interest given the absence of any intent or action by Applicant or the Contributor to influence the selection

For the Commission, by the Division of Investment Management, under delegated authority.

#### Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–17715 Filed 7–17–15; 8:45 am]

BILLING CODE 8011-01-P

### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-75449; File No. SR-NYSEARCA-2015-55]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services

July 14, 2015.

Pursuant to Section 19(b)(1) <sup>1</sup> of the Securities Exchange Act of 1934 (the "Act") <sup>2</sup> and Rule 19b–4 thereunder, <sup>3</sup> notice is hereby given that, on June 24, 2015, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services ("Fee Schedule") to (i) raise the fee for Market and Auction-Only Orders executed in an Opening, Market Order or Trading Halt Auction; (ii) modify the credits the Exchange provides for routing certain orders to the New York Stock Exchange LLC ("NYSE"); and (iii) revise the Tape B Step Up Tier. The Exchange proposes to implement the changes on July 1, 2015.

The text of the proposed rule change is available on the Exchange's Web site at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below,

of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The Exchange proposes to amend the Fee Schedule to (i) raise the Tier 1 and Tier 2 fee for Market and Auction-Only Orders executed in an Opening, Market Order or Trading Halt Auction and make corresponding changes in the Basic Rate pricing; (ii) modify the Tier 1 and Tier 2 credits the Exchange provides for routing certain orders to the NYSE and make corresponding changes in the Basic Rate pricing; and (iii) revise the Tape B Step Up Tier. The Exchange proposes to implement the fee changes on July 1, 2015.

For Tier 1 and Tier 2, the Exchange currently charges \$0.0010 per share for Market and Auction-Only Orders executed in an Opening, Market Order or Trading Halt Auction with a cap of \$20,000 per month per Equity Trading Permit ID. The Exchange proposes to raise this fee from \$0.0010 to \$0.0015 per share. The Exchange is not proposing any change to the cap.

The Exchange proposes to make corresponding changes to the Basic Rate pricing section of the Fee Schedule. Specifically, in the Basic Rate pricing section, the current fee for Market and Auction-Only Orders executed in an Opening, Market Order or Trading Halt Auction is \$0.0010 per share, with a cap of \$20,000 per month per Equity Trading Permit ID. The Exchange proposes to raise this fee to \$0.0015 per share. The Exchange is not proposing any change to the cap.

In a recent rule filing, the NYSE has proposed to modify its fee structure for equities transaction, including changes to the rates for providing liquidity, to become effective July 1, 2015.4 The Exchange's current credits for routing orders to NYSE are closely related to the NYSE's rates, including credits for providing liquidity, and the Exchange is proposing an adjustment to its routing credits to maintain the existing relationship to the rates proposed by the NYSE. Specifically, for Tier 1 and Tier 2 PO+ orders,<sup>5</sup> the current Exchange credit for orders that are routed to the NYSE that provide liquidity to the

NYSE is \$0.0015 per share, which is equal to the current NYSE rebate for execution of customer orders that add liquidity to the NYSE. The Exchange is proposing to lower the credits for routing Tier 1 and Tier 2 PO+ Orders to the NYSE by the same amount (\$0.0001) as the decrease in the corresponding NYSE credit. The proposed new credit for such orders routed to the NYSE that provide liquidity to the NYSE would be \$0.0014 per share. This proposed fee change would maintain the current relationship with NYSE rates.

The Exchange proposes to make corresponding changes to the Basic Rate pricing section of the Fee Schedule. Currently, the credit for PO+ Orders that provide liquidity to the NYSE is set at \$0.0015 per share. The Exchange proposes to lower this credit to \$0.0014 per share. Again, this proposed fee change would maintain the current relationship with NYSE rates.

Finally, the Exchange proposes to revise the Tape B Step Up Tier. Currently, ETP Holders and Market Makers, that, on a daily basis, measured monthly, directly execute providing volume in Tape B Securities during a billing month ("Tape B Adding ADV") that is equal to at least 0.275% of the U.S. Tape B Consolidated Average Daily Volume ("Tape B CADV") for the billing month over the ETP Holder's or Market Maker's May 2013 Tape B Adding ADV taken as a percentage of Tape B CADV ("Tape B Baseline % CADV") receive a credit of \$0.0004 per share for orders that provide liquidity to the Exchange in Tape B Securities, which is in addition to the ETP Holder's Tiered or Basic Rate credit(s). The Exchange proposes to specify in the Fee Schedule that ETP Holders that qualify for the Cross-Asset Tier would not be eligible to qualify for the Tape B Step Up Tier. The Exchange believes that the credit of \$0.0030 per share is sufficient that an ETP Holder that qualifies for the Cross-Asset Tier should not also receive the increased credits applicable to the Tape B Step Up Tier. Similar to Retail Order Tier ETP Holders and Market Makers, who are currently ineligible to qualify for the Tape B Step Up Tier, the Exchange proposes to exclude Cross-Asset Tier ETP Holders from also qualifying for the Tape B Step Up Tier.

The proposed changes are not otherwise intended to address any other issues, and the Exchange is not aware of any problems that ETP Holders would have in complying with the proposed changes.

#### 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with

<sup>&</sup>lt;sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>&</sup>lt;sup>2</sup> 15 U.S.C. 78a

<sup>3 17</sup> CFR 240.19b-4.

<sup>&</sup>lt;sup>4</sup> See SR-NYSE-2015-30.

<sup>&</sup>lt;sup>5</sup> A PO+ Order is a Primary Only Order (*i.e.*, a market or limit order that is to be routed to the primary market) that is entered for participation in the primary market, other than for participation in the primary market opening or primary market reopening. See NYSE Arca Equities Rule 7.31(f)(1)(C).

Section 6(b) of the Act,<sup>6</sup> in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,<sup>7</sup> in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed fee increase for Market and Auction-Only Orders executed in an Opening, Market Order or Trading Halt Auction are reasonable because they are the same as the fees imposed by at least one other exchange.<sup>8</sup> In addition, the proposed fee changes are equitable and not unfairly discriminatory because they apply uniformly to all similarly situated ETP Holders.

The Exchange believes that the proposed changes to routing credits for PO+ Orders that provide liquidity to the NYSE are reasonable because the Exchange's credits for routing such orders are closely related to the NYSE's rebates for its members for providing liquidity, and the proposed change is consistent with the change proposed by the NYSE to lower its rebate for providing liquidity. The proposed change would result in maintaining the existing relationship between the two sets of fees. In addition, the Exchange believes that the proposed rule change, which would result in a decrease in the per share credit for PO+ Orders routed to the NYSE that provide liquidity to the NYSE, would thereby align the rate that the Exchange provides to ETP Holders with the rate that NYSE provides to its members for providing liquidity. Further, the proposed change is equitable and not unfairly discriminatory because the rebate reduction would apply uniformly across pricing tiers and all similarly situated ETP Holders would be subject to the same credit.

The Exchange believes that prohibiting Cross-Asset Tier ETP Holders from qualifying for the Tape B Step Up Tier is reasonable, equitable and not unfairly discriminatory because ETP Holders that qualify for the Cross-Asset Tier would already receive a higher credit of \$0.0030 before the Tape B Step Up Credit, which is higher than other tiers with the Tape B Step Up credit. For example, Tier 1 ETP Holders that qualify for Tape B Step Up Tier would receive a Tier 1 credit of \$0.0023

plus a Tape B Step Up credit of \$0.0004 for a total credit of \$0.0027, compared with the standalone Cross-Asset credit of \$0.0030. The Exchange notes that Cross-Asset Tier ETP Holders and Market Makers currently do not qualify for Tape C Step Up Tier 2 credit.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition. For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,<sup>9</sup> the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In particular, the proposed routing credit changes would not place a burden on competition because the Exchange is seeking to align its credits with the credits provided by the NYSE.<sup>10</sup> In addition, the proposed change to the Exchange's fee for Market and Auction-Only Orders executed in an Opening, Market Order or Trading Halt Auction is consistent with the fee charged by at least one other exchange.11

The Exchange does not believe prohibiting Cross-Asset Tier ETP Holders from qualifying for increased credit(s) will impair ETP Holders' ability to compete. The Exchange already provides a credit for Cross-Asset Tier ETP Holders and ETP Holders impacted by the proposed change may readily adjust their trading behavior to maintain or increase their credits or decrease their fees in a favorable manner.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change promotes a competitive environment.

No written comments were solicited or received with respect to the proposed rule change.

#### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section  $19(b)(3)(A)^{12}$  of the Act and subparagraph (f)(2) of Rule  $19b-4^{13}$  thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) 14 of the Act to determine whether the proposed rule change should be approved or disapproved.

#### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission's Internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@* sec.gov. Please include File Number SR–NYSEARCA–2015–55 on the subject line.

#### Paper Comments

• Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. All submissions should refer to File Number SR–NYSEARCA–2015–55. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

<sup>&</sup>lt;sup>6</sup> 15 U.S.C. 78f(b).

<sup>&</sup>lt;sup>7</sup> 15 U.S.C. 78f(b)(4) and (5).

<sup>&</sup>lt;sup>8</sup> See NASDAQ Crossing Network Fees at http://www.nasdaqtrader.com/

Trader.aspx?id=PriceListTrading2.

<sup>9 15</sup> U.S.C. 78f(b)(8).

<sup>&</sup>lt;sup>10</sup> See supra note 4.

<sup>&</sup>lt;sup>11</sup> See supra note 8.

<sup>12 15</sup> U.S.C. 78s(b)(3)(A).

<sup>13 17</sup> CFR 240.19b-4(f)(2).

<sup>14 15</sup> U.S.C. 78s(b)(2)(B).

Internet Web site (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Section, 100 F Street NE., Washington, DC 20549-1090. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at www.nyse.com. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEARCA-2015-55 and should be submitted on or before August 7, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>15</sup>

#### Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-17660 Filed 7-17-15; 8:45 am]

BILLING CODE 8011-01-P

### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-75446; File No. SR-Phlx-2015-58]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Exchange's Pricing Schedule under Section VIII With Respect to Execution and Routing of Orders in Securities Priced at \$1 or More per Share

July 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b–4² thereunder, notice is hereby given that, on June 30, 2015, NASDAQ OMX PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The

Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Pricing Schedule under Section VIII, entitled "NASDAQ OMX PSX FEES," with respect to execution and routing of orders in securities priced at \$1 or more per share.

While the changes proposed herein are effective upon filing, the Exchange has designated that the amendments be operative on July 1, 2015.

The text of the proposed rule change is available on the Exchange's Web site at *http://* 

nasdaqomxphlx.cchwallstreet.com/, at the principal office of the Exchange, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

#### 1. Purpose

The purpose of the proposed rule change is to amend certain credits for order execution and routing applicable to the use of the order execution and routing services of the NASDAQ OMX PSX System ("PSX") by member organizations for all securities traded at \$1 or more per share.

The Exchange will increase non-displayed order credits for all orders with midpoint pegging that provide liquidity through PSX. Specifically, the credit tiers for non-displayed orders of a \$0.0015 per share executed credit for orders with midpoint pegging that provide liquidity entered by a member organization that provides 1,000,000 shares or more average daily volume of non-displayed liquidity during the month and the credit tier for non-displayed orders of \$0.0010 per share

executed will be replaced with a single credit tier of \$0.0020 per share executed for all orders with midpoint pegging <sup>3</sup> that provide liquidity to create further incentives to provide midpoint liquidity on PSX for the benefit of investors and other market participants.

#### 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,<sup>4</sup> in general, and with Section 6(b)(4) and 6(b)(5) of the Act,<sup>5</sup> in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system which the Exchange operates or controls, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed increases to the credits in the fee schedule under the Exchange's Pricing Schedule under Section VIII are reflective of the Exchange's ongoing efforts to use pricing incentive programs to attract order flow to the Exchange and improve market quality. The goal of these pricing incentives is to provide meaningful incentives for members to increase their participation on the Exchange.

The Exchange is proposing to increase non-displayed order credits for all orders with midpoint pegging that provide liquidity through PSX by replacing the existing two such tiers with a single tier. Specifically, the credit tiers for non-displayed orders of a \$0.0015 per share executed credit for orders with midpoint pegging that provide liquidity entered by a member organization that provides 1,000,000 shares or more average daily volume of non-displayed liquidity during the month and the credit tier for nondisplayed orders of \$0.0010 per share executed will be replaced with a single credit tier of \$0.0020 per share executed for all orders with midpoint pegging that provide liquidity.

The Exchange believes the proposed change is reasonable because the increase to the credit for all orders with midpoint pegging that provide liquidity provides member organizations with a uniform credit designed to incentivize increased midpoint liquidity on PSX. Additionally, the Exchange believes providing a greater credit will act as an incentive for members to increase their participation on the Exchange.

<sup>15 17</sup> CFR 200.30-3(a)(12).

<sup>&</sup>lt;sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>&</sup>lt;sup>2</sup> 17 CFR 240.19b-4.

<sup>&</sup>lt;sup>3</sup> Including the Midpoint Peg Post-Only Order recently filed with the Commission, once effective and operative. *See* SR-PHLX-2015-056 (as recently filed).

<sup>&</sup>lt;sup>4</sup> 15 U.S.C. 78f.

<sup>&</sup>lt;sup>5</sup> 15 U.S.C. 78f(b)(4) and (5).

The Exchange believes that the proposed rule change is consistent with an equitable allocation of fees and is not unfairly discriminatory because the single credit for all orders with midpoint pegging that provide liquidity is uniformly available to all members and affects all members equally and in the same way.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.6 Phlx notes that it operates in a highly competitive market in which market participants can readily favor dozens of different competing exchanges and alternative trading systems if they deem charges at a particular venue to be excessive, or credit opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its charges and credits to remain competitive with other exchanges. Because competitors are free to modify their own charges and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which changes to charges and credits in this market may impose any burden on competition is extremely limited.

In this instance, the changes to the credits for all orders with midpoint pegging that provide liquidity do not impose a burden on competition because Exchange membership is optional and is the subject of competition from other exchanges. The increased credit is reflective of the intent to increase the order flow on the Exchange. For these reasons, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets. Moreover, because there are numerous competitive alternatives to the use of the Exchange, it is likely that the Exchange will lose market share as a result of the changes if they are unattractive to market participants.

Accordingly, Phlx does not believe that the proposed rule changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets. C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

#### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

#### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission's Internet comment form (http://www.sec.gov/rules/sro.shtml); or
- Send an email to *rule-comments@ sec.gov*. Please include File Number SR–Phlx–2015–58 on the subject line.

#### Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. All submissions should refer to File Number SR-Phlx-2015-58. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (http://www.sec.gov/ rules/sro.shtml). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2015-58 and should be submitted on or before August 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>8</sup>

#### Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-17657 Filed 7-17-15; 8:45 am]

BILLING CODE 8011-01-P

#### **DEPARTMENT OF STATE**

[Public Notice: 9196]

Culturally Significant Objects Imported for Exhibition Determinations: "New Objectivity: Modern German Art in the Weimar Republic 1919–1933" Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, et seq.; 22 U.S.C. 6501 note, et seq.), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "New Objectivity: Modern German Art in the Weimar Republic 1919-1933," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Los Angeles County Museum of Art, Los Angeles, California, from on or about October 4, 2015, until on or about January 18,

2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@ state.gov). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: July 13, 2015.

#### Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–17728 Filed 7–17–15; 8:45 am]

BILLING CODE 4710-05-P

#### **DEPARTMENT OF STATE**

[Public Notice: 9195]

Culturally Significant Objects Imported for Exhibition Determinations: "Ancient Egypt Transformed: The Middle Kingdom" Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E. O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, et seq.; 22 U.S.C. 6501 note, et seq.), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Ancient Egypt Transformed: The Middle Kingdom," imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Metropolitan Museum of Art, New York, New York, from on or about October 12, 2015, until on or about January 24, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the Federal Register.

**FOR FURTHER INFORMATION CONTACT:** For further information, including a list of the imported objects, contact the Office

of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@ state.gov). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: July 14, 2015.

#### Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–17724 Filed 7–17–15; 8:45 am]

BILLING CODE 4710-05-P

#### **DEPARTMENT OF STATE**

[Public Notice: 9197]

Culturally Significant Objects Imported for Exhibition Determinations: "Strength and Splendor: Wrought Iron From the Musée Le Secq des Tournelles" Exhibition

**SUMMARY:** Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E. O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, et seq.; 22 U.S.C. 6501 note, et seq.), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236-3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition "Strength and Splendor: Wrought Iron from the Musée Le Secq des Tournelles,' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at The Barnes Foundation, Philadelphia, Pennsylvania, from on or about September 19, 2015, until on or about January 4, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the Federal Register.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: section2459@ state.gov). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: July 13, 2015.

#### Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015-17727 Filed 7-17-15; 8:45 am]

BILLING CODE 4710-05-P

#### DEPARTMENT OF TRANSPORTATION

#### **Federal Highway Administration**

### Notice of Final Federal Agency Actions on Proposed Highway in Hawaii

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Notice of limitation on claims for judicial review of actions by FHWA and other Federal agencies.

**SUMMARY:** This notice announces actions taken by FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(1)(1). The actions relate to the Queen Ka'ahumanu Highway Widening project located in North Kona, in the State of Hawai'i. These actions grant licenses, permits, and approvals for the project.

DATES: By this notice, FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(1). A claim seeking judicial review of the Federal agency actions on the listed highway project will be barred unless the claim is filed on or before December 17, 2015. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

#### FOR FURTHER INFORMATION CONTACT:

Mayela Sosa, Division Administrator, Federal Highway Administration, 300 Ala Moana Boulevard, Box 50206, Honolulu, Hawaii 96850, Telephone: (808) 541–2700; or Raymond J. McCormick, Highways Administrator, State of Hawaii Department of Transportation, 869 Punchbowl Street, Honolulu, Hawaii 96813, Telephone: (808) 587–2220;

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA and other Federal agencies have taken final agency actions by issuing licenses, permits, and approvals for the following: In 1996, FHWA and HDOT published the EA to widen Queen Kaʻahumanu Highway from a two lane to four lane facility. The FHWA issued a Finding of No Significant Impact on June 10, 1996. The original project limits extended from Palani Road to Keahole Airport Access Road, a total project length of 8.0 miles. However, due to funding constraints, the project was split into

two phases. Phase 1 covered widening and improvements on Queen Ka'ahumanu Highway from Palani Road to Kealakehe Parkway, a distance of 2.8 miles, while Phase 2 covers the remaining 5.2 miles from Kealakehe Parkway to Keahole Airport Access Road. Construction of Phase 1 was completed in 2009.

These actions by the Federal agencies, and the laws under which such actions were taken, are described in the 1996 Environmental Assessment (EA), FONSI, and May 15, 2015, Reevaluation, and in other documents in the FHWA administrative record. The EA, FONSI, Reevaluation and other documents in the FHWA administrative record are available by contacting HDOT or FHWA at the addresses provided above.

This notice applies to all Federal agency decisions on the project as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

- 1. *General:* National Environmental Policy Act [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109 and 23 U.S.C. 128].
- 2. *Air:* Clean Air Act, as amended [42 U.S.C. 7401–767l(q)].
- 3. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].
- 4. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544]; Anadromous Fish Conservation Act [16 U.S.C. 757(a)–757(g)]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801 et seq.].
- 5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) et seq.]; Archaeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–ll]; Archaeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act [25 U.S.C. 3001–3013].
- 6. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)-2000(d)(l)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act [7 U.S.C. 4201–4209]; the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended [42 U.S.C. 61].

- 7. Wetlands and Water Resources: Clean Water Act, 33 U.S.C. 1251–1377 (Section 404, Section 401, Section 319); Coastal Zone Management Act [16 U.S.C. 1451–1464]; Land and Water Conservation Fund [16 U.S.C. 4601–4604]; Safe Drinking Water Act [42 U.S.C. 300(f)–300G)(6)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wetlands Mitigation [23 U.S.C. 103(b)(6)(m),133(b)(11)]; Flood Disaster Protection Act [42 U.S.C. 4001–4128].
- 9. Executive Orders: E.O. 11990
  Protection of Wetlands; E.O. 11988 and 13690, Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

**Authority:** 23 U.S.C. 139(1)(1).

Issued on: July 9, 2015.

#### Mayela Sosa,

Division Administrator, Honolulu, HI. [FR Doc. 2015–17700 Filed 7–17–15; 8:45 am] BILLING CODE 4910–22–P

#### **DEPARTMENT OF TRANSPORTATION**

#### **Federal Railroad Administration**

[Docket No. FRA-2015-007-N-19]

Agency Request for Emergency Processing of Collection of Information by the Office of Management and Budget

**AGENCY:** Federal Railroad Administration (FRA), United States Department of Transportation (USDOT). **ACTION:** Notice.

**SUMMARY:** FRA hereby gives notice that it is submitting the following Information Collection request (ICR) to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995.

FRA requests that OMB authorize the collection of information identified by July 24, 2015, for a period of 180 days.

FOR FURTHER INFORMATION CONTACT: A copy of this individual ICR, with applicable supporting documentation, may be obtained by telephoning FRA's Office of Safety Clearance Officer: Robert Brogan (tel. (202) 493-6292) or FRA's Office of Administration Clearance Officer: Kimberly Toone (tel. (202) 493-6132) (these numbers are not toll-free); or by contacting Mr. Brogan via facsimile at (202) 493-6216 or Ms. Toone via facsimile at (202) 493-6497, or via email by contacting Mr. Brogan at Robert.Brogan@dot.gov; or by contacting Ms. Toone at Kim. Toone@dot.gov. Comments and questions about the ICR identified below should be directed to OMB's Office of Information and Regulatory Affairs, Attn: FRA OMB Desk Officer.

SUPPLEMENTARY INFORMATION: The statutory deadline for Positive Train Control (PTC) system implementation is December 31, 2015, less than 6 months away. Congress and FRA are concerned that the railroads will not make the statutory deadline. To date, the vast majority of railroads have not submitted, in accordance with 49 CFR 236.1009 and 236.1015, a PTC Safety Plan (PTCSP) and have not submitted, in accordance with 49 CFR 236.1035, a request for testing approval to support a PTCSP, which is necessary to achieve PTC System Certification and operate in revenue service. So that Congress and FRA may better understand the status of each railroad's implementation efforts, FRA is seeking accurate and current information, with periodic updates, under its investigative authority pursuant to 49 U.S.C. 20103, 20107, and 20902, and 49 CFR 236.1009(h). The railroads' responses will help inform FRA of the current PTC implementation status.

FRA is requesting Emergency processing approval by July 24, 2015, because FRA cannot reasonably comply with normal clearance procedures on account of use of normal clearance procedures is reasonably likely to disrupt the collection of information. The proposed collection of information is summarized below.

Title: Positive Train Control (PTC) Implementation Status Update Questionnaire.

Reporting Burden:

PTC implementation status update	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
Questionnaire to be completed by railroads required to implement PTC.	38 Railroads	456 Surveys	10 minutes	76

Form Number(s): N/A.
Respondent Universe: 38 Railroads.
Frequency of Submission: Monthly.
Total Estimated Responses: 456
Surveys.

Total Estimated Annual Burden: 380 hours.

Status: Emergency Review.
Pursuant to 44 U.S.C. 3507(a) and 5
CFR 320.5(b), 1320.8(b)(3)(vi), FRA
informs all interested parties that it may
not conduct or sponsor, and a
respondent is not required to respond
to, a collection of information unless it
displays a currently valid OMB control

Authority: 44 U.S.C. 3501-3520.

Issued in Washington, DC, on July 15, 2015.

#### Rebecca Pennington,

number.

Chief Financial Officer.

[FR Doc. 2015-17689 Filed 7-17-15; 8:45 am]

BILLING CODE 4910-06-P

#### **DEPARTMENT OF THE TREASURY**

# Public Input on Expanding Access to Credit Through Online Marketplace Lending

**AGENCY:** Office of the Undersecretary for Domestic Finance, Department of the Treasury.

**ACTION:** Notice and request for information.

**SUMMARY:** Online marketplace lending refers to the segment of the financial services industry that uses investment capital and data-driven online platforms to lend to small businesses and consumers. The Treasury Department is seeking public comment through this Request For Information (RFI) on (i) the various business models of and products offered by online marketplace lenders to small businesses and consumers; (ii) the potential for online marketplace lending to expand access to credit to historically underserved market segments; and (iii) how the financial regulatory framework should evolve to support the safe growth of this industry.12

**DATES:** Submit comments on or before: August 31, 2015.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via U.S. mail or commercial delivery. We will not accept comments by fax or by email. To ensure that we do not receive duplicate copies, please submit your comments only one time. In addition, please include the Docket ID and the term "Marketplace Lending RFI" at the top of your comments.

- Federal eRulemaking Portal: You are encouraged to submit comments electronically through www.regulations.gov. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under a tab titled "Are you new to the site?" Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt, and enables the Department to make them available to the public.
- U.S. Mail or Commercial Delivery: If you mail your comments, address them to Laura Temel, Attention: Marketplace Lending RFI, U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW., Room 1325, Washington, DC 20220.

loans, deposit advance products, and certain highcost installment loans and open-end loans. See 'Small Business Advisory Review Panel for Potential Rulemakings for Payday, Vehicle Title, and Similar Loans: Outline of Proposals Under Consideration and Alternatives Considered" (March 26, 2015), available at http:// files.consumerfinance.gov/f/201503\_cfpb\_outlineof-the-proposals-from-small-business-reviewpanel.pdf. The potential content, effects, and policy underpinnings of CFPB rules are outside the scope of this RFI, and comments responding to this RFI should not address these CFPB rulemakings or their potential effects on marketplace lending to consumers. Thus, the RFI only seeks comment on online marketplace lending not covered in the potential rulemakings, which, under the current framework, would include comments on the making or facilitating of a loan by online lender to consumers with a term of more than 45 days and an annual percentage rate (as defined in 10 U.S.C. 987(i)(4)) that (I) does not exceed 36% or (II) exceeds 36% provided the loan neither provides for repayment directly from a consumer's account or paycheck nor creates a non-purchase money security interest in a vehicle. This framework is currently under discussion, however, and the CFPB may ultimately change the scope of any proposed or final CFPB regulation.

<sup>2</sup> The activities on online marketplace lending platforms also may entail the offering of securities that are subject to the federal securities laws.

• Privacy Note: The Department's policy for comments received from members of the public (including comments submitted by mail and commercial delivery) is to make these submissions available for public viewing in their entirety on the Federal eRulemaking Portal at <a href="https://www.regulations.gov">www.regulations.gov</a>. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available on the Internet.

FOR FURTHER INFORMATION CONTACT: For general inquiries, submission process questions or any additional information, please email Marketplace\_Lending@treasury.gov or call (202) 622–1083. All responses to this Notice and Request for Information should be submitted via http://www.regulations.gov to ensure consideration. If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

#### SUPPLEMENTARY INFORMATION:

#### I. Request for Information

The Treasury Department is seeking public comment through this RFI to study (i) the various business models of and products offered by online marketplace lenders to small businesses and consumers; (ii) the potential for online marketplace lending to expand access to credit to historically underserved market segments; and (iii) how the financial regulatory framework should evolve to support the safe growth of this industry.

In particular, the Treasury
Department is interested in responses to
the following questions. We also seek
any additional information beyond
these questions that market participants
believe would assist in our efforts to
become better informed of the impact of
online marketplace lending on small
businesses, consumers, and the broader
economy.

Online marketplace lenders may be subject to regulations promulgated by various agencies including, but not limited to, the CFPB and the Federal Trade Commission.

Respondents should provide as much detail as possible about the particular type of institution, product (e.g., small business loan, consumer loan), business model, and practices to which their

<sup>&</sup>lt;sup>1</sup> The Consumer Financial Protection Bureau (CFPB) has broad authority governing standards that may apply to a variety of consumer loans issued through this segment, and it has recently announced that it is considering proposing rules that would apply to payday loans, vehicle title

comments apply. Responses to this RFI will be made public.

#### II. Purpose

Historically, many American households, small businesses, and promising new enterprises have faced barriers in accessing affordable credit from traditional lenders. To date, the large majority of online marketplace consumer loans have been originated to prime or near-prime consumers to refinance existing debt. Online marketplace lending has filled a need for these borrowers by often delivering lower costs and faster decision times than traditional lenders. Non-prime consumers face other challenges in obtaining traditional bank-originated credit, particularly due to having thin or no credit files or damaged credit. Moreover, high underwriting costs can make it uneconomical to make smallvalue consumer loans. For example, it can cost the same amount to underwrite a \$300 consumer loan as a \$3,000 loan. Small-value loans to non-prime consumers thus have often come with triple digit annual percentage rates (APR). Some online marketplace lenders, however, are developing product structures and underwriting models that might allow making loans to non-prime borrowers at lower rates.3

With respect to small businesses, a number of studies have shown that these borrowers are more dependent on community banks for financing than larger firms, which have access to other forms of finance including public debt and equity markets. While larger businesses typically rely on banks for 30 percent of their financing, small businesses receive 90 percent of their financing from banks.4 Small business lending, however, has high search, transaction, and underwriting costs for banks relative to potential revenue—it costs about the same to underwrite a \$5 million dollar loan as a \$200,000 loan 5—and many small business owners report they are unable to access the credit needed to grow their business. According to Federal Reserve survey data released in February 2015, "a majority of small firms (under \$1 million in annual revenues) and startups (under 5 years in business)

were unable to secure any credit in the prior year." <sup>6</sup>

The challenge is particularly acute for small business loans of lower value and shorter terms. More than half of small businesses that applied for credit in 2014 sought loans of \$100,000 or less. At the same time, more than two thirds of businesses with under \$1 million in annual revenue that applied for credit received less than the full amount that they sought and half received none.7 Technology-enabled credit provisioning offers the potential to reduce transaction costs for these products, while investment capital may offer a new source of financing for historically underserved markets. The 2014 Small Business Credit Survey indicated that almost 20 percent of applicants sought credit from an online lender.

While online marketplace lending is still a very small component of the small business and consumer lending market, it is a rapidly developing and fast-growing sector that is changing the credit marketplace. In less than a decade, online marketplace lending has grown to an estimated \$12 billion in new loan originations in 2014, the majority of which is consumer lending.8 Through this RFI, Treasury is seeking to study the potential for online marketplace lending to expand access to credit and how the financial regulatory framework should evolve to support the safe growth of this industry.

#### III. Background

Online marketplace lending broadly refers to the segment of the financial services industry that uses investment capital and data-driven online platforms to lend either directly or indirectly to small businesses and consumers. This segment initially emerged with companies giving investors the ability to provide financing that would be used to fund individual borrowers through what became known as a "peer-to-peer" model. However, it has since evolved to include a diverse set of individual and institutional credit investors who seek to provide financing that ultimately is used to fund small business and consumer loans of various types to gain access to additional credit channels and favorable rates of return.

Companies operating in this industry tend to fall into three general categories: (1) Balance sheet lenders that retain

credit risk in their own portfolios and are typically funded by venture capital, hedge fund, or family office investments; (2) online platforms (formerly known as "peer-to-peer") that, through the sale of securities such as member-dependent notes, obtain the financing to enable third parties to fund borrowers and, due to the contingent nature of the payment obligation on such securities, do not retain credit risk that the borrowers will not pay; and (3) bank-affiliated online lenders that are funded by a commercial bank, often a regional or community bank, originate loans and directly assume the credit risk.

Additionally, some of these companies have adopted a business model in which they partner and have agreements with banks. In these arrangements, the bank acts as the lender to borrowers that apply on the platform. The loans are then purchased by a second party — either by an investor, in which the transaction is facilitated by the marketplace lender, or by the marketplace lender itself, which funds the loan purchase by note sales. While the loans are not pooled, small investors can obtain a return by making small investments in a number of notes offered by a marketplace lender through its platforms.

Online marketplace lenders share key similarities. They provide funding through convenient online loan applications and most have no retail branches. They use electronic data sources and technology-enabled underwriting models to automate processes such as determining a borrower's identity and credit risk. These data sources might include traditional underwriting statistics (e.g., income and debt obligations), but also often include other forms of information, including novel data points or combinations. Online marketplace lenders typically provide borrowers with faster access to credit than the traditional face-to-face credit application process. Small business online market place lenders, provide small businesses with lower value (less than \$100,000) and shorter terms.

#### Key Questions

1. There are many different models for online marketplace lending including platform lenders (also referred to as "peer-to-peer"), balance sheet lenders, and bank-affiliated lenders. In what ways should policymakers be thinking about market segmentation; and in what ways do different models raise different policy or regulatory concerns?

2. According to a survey by the National Small Business Association, 85

<sup>&</sup>lt;sup>3</sup> As noted elsewhere, the CFPB is contemplating issuing a rule that would regulate "payday" and related loans, including loans with terms greater than 45 days and an APR greater than 36%, if the loan also provides for repayment directly from a consumer's account or paycheck or includes a non-purchase money security interest in a vehicle. Such consumer loans are outside the scope of this RFI.

 $<sup>^4\,\</sup>mbox{``2011}$  Economic Report of the President,'' Council of Economic Advisors. The White House.

<sup>&</sup>lt;sup>5</sup> "The Future of Finance," Goldman Sachs Equity Research, March 3, 2015.

<sup>6 &</sup>quot;The Joint Small Business Credit Survey, 2014," a collaboration among the Federal Reserve Banks of New York, Atlanta, Cleveland and Philadelphia. Released February 2015.

<sup>7</sup> Ibid.

<sup>8 &</sup>quot;Global Marketplace Lending: Disruptive Innovation in Financials," Morgan Stanley Research, May 2015.

percent of small businesses purchase supplies online, 83 percent manage bank accounts online, 82 percent maintain their own Web site, 72 percent pay bills online, and 41 percent use tablets for their businesses.9 Small businesses are also increasingly using online bookkeeping and operations management tools. As such, there is now an unprecedented amount of online data available on the activities of these small businesses. What role are electronic data sources playing in enabling marketplace lending? For instance, how do they affect traditionally manual processes or evaluation of identity, fraud, and credit risk for lenders? Are there new opportunities or risks arising from these data-based processes relative to those used in traditional lending?

- 3. How are online marketplace lenders designing their business models and products for different borrower segments, such as:
- Small business and consumer borrowers;
  - Subprime borrowers;
- Borrowers who are "unscoreable" or have no or thin files:

Depending on borrower needs (e.g., new small businesses, mature small businesses, consumers seeking to consolidate existing debt, consumers seeking to take out new credit) and other segmentations?

- 4. Is marketplace lending expanding access to credit to historically underserved market segments?
- 5. Describe the customer acquisition process for online marketplace lenders. What kinds of marketing channels are used to reach new customers? What kinds of partnerships do online marketplace lenders have with traditional financial institutions, community development financial institutions (CDFIs), or other types of businesses to reach new customers?
- 6. How are borrowers assessed for their creditworthiness and repayment ability? How accurate are these models in predicting credit risk? How does the assessment of small business borrowers differ from consumer borrowers? Does

the borrower's stated use of proceeds affect underwriting for the loan?

- 7. Describe whether and how marketplace lending relies on services or relationships provided by traditional lending institutions or insured depository institutions. What steps have been taken toward regulatory compliance with the new lending model by the various industry participants throughout the lending process? What issues are raised with online marketplace lending across state lines?
- 8. Describe how marketplace lenders manage operational practices such as loan servicing, fraud detection, credit reporting, and collections. How are these practices handled differently than by traditional lending institutions? What, if anything, do marketplace lenders outsource to third party service providers? Are there provisions for back-up services?
- 9. What roles, if any, can the federal government play to facilitate positive innovation in lending, such as making it easier for borrowers to share their own government-held data with lenders? What are the competitive advantages and, if any, disadvantages for non-banks and banks to participate in and grow in this market segment? How can policymakers address any disadvantages for each? How might changes in the credit environment affect online marketplace lenders?
- 10. Under the different models of marketplace lending, to what extent, if any, should platform or "peer-to-peer" lenders be required to have "skin in the game" for the loans they originate or underwrite in order to align interests with investors who have acquired debt of the marketplace lenders through the platforms? Under the different models, is there pooling of loans that raise issues of alignment with investors in the lenders' debt obligations? How would the concept of risk retention apply in a non-securitization context for the different entities in the distribution chain, including those in which there is no pooling of loans? Should this concept of "risk retention" be the same for other types of syndicated or participated loans?
- 11. Marketplace lending potentially offers significant benefits and value to

- borrowers, but what harms might online marketplace lending also present to consumers and small businesses? What privacy considerations, cybersecurity threats, consumer protection concerns, and other related risks might arise out of online marketplace lending? Do existing statutory and regulatory regimes adequately address these issues in the context of online marketplace lending?
- 12. What factors do investors consider when: (i) Investing in notes funding loans being made through online marketplace lenders, (ii) doing business with particular entities, or (iii) determining the characteristics of the notes investors are willing to purchase? What are the operational arrangements? What are the various methods through which investors may finance online platform assets, including purchase of securities, and what are the advantages and disadvantages of using them? Who are the end investors? How prevalent is the use of financial leverage for investors? How is leverage typically obtained and deployed?
- 13. What is the current availability of secondary liquidity for loan assets originated in this manner? What are the advantages and disadvantages of an active secondary market? Describe the efforts to develop such a market, including any hurdles (regulatory or otherwise). Is this market likely to grow and what advantages and disadvantages might a larger securitization market, including derivatives and benchmarks, present?
- 14. What are other key trends and issues that policymakers should be monitoring as this market continues to develop?

Guidance for Submitting Documents: We ask that each respondent include the name and address of his or her institution or affiliation, and the name, title, mailing and email addresses, and telephone number of a contact person for his or her institution or affiliation, if any.

Dated: July, 13, 2015.

David G. Clunie,

Executive Secretary,

[FR Doc. 2015–17644 Filed 7–17–15; 8:45 am]

BILLING CODE 4810-25-P

<sup>&</sup>lt;sup>9</sup> "2013 Small Business Technology Survey," National Small Business Association.



# FEDERAL REGISTER

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#### Part II

### **Environmental Protection Agency**

40 CFR Part 82

Protection of Stratospheric Ozone: Change of Listing Status for Certain Substitutes Under the Significant New Alternatives Policy Program; Final Rule

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 82

[EPA-HQ-OAR-2014-0198; FRL-9926-55-OAR]

#### RIN 2060-AS18

Protection of Stratospheric Ozone: Change of Listing Status for Certain Substitutes Under the Significant New Alternatives Policy Program

**AGENCY:** Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** This action changes the status from acceptable to unacceptable; acceptable, subject to use conditions; or acceptable, subject to narrowed use limits for a number of substitutes, pursuant to the U.S. Environmental Protection Agency's Significant New Alternatives Policy program. We make these changes based on information showing that other substitutes are available for the same uses that pose lower risk overall to human health and the environment. Specifically, this action changes the listing status for certain hydrofluorocarbons in various end-uses in the aerosols, refrigeration and air conditioning, and foam blowing sectors. This action also changes the status from acceptable to unacceptable for certain hydrochlorofluorocarbons being phased out of production under the Montreal Protocol on Substances that Deplete the Ozone Layer and section 605(a) of the Clean Air Act.

**DATES:** This rule is effective on August 19, 2015.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2014-0198. All documents in the docket are listed in the index. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed in the electronic docket and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and

the telephone number for the Air and Radiation Docket is (202) 566–1742.

#### FOR FURTHER INFORMATION CONTACT:

Margaret Sheppard, Stratospheric Protection Division, Office of Atmospheric Programs, Mail Code 6205J, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number (202) 343–9163; fax number (202) 343–2338, email address: sheppard.margaret@epa.gov. Notices and rulemakings under EPA's Significant New Alternatives Policy (SNAP) program are available on EPA's Stratospheric Ozone Web site at www.epa.gov/ozone/snap/regs.

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#### I. General Information

#### A. Executive Summary

Under section 612 of the Clean Air Act (CAA), EPA reviews substitutes within a comparative risk framework. More specifically, section 612 provides that EPA must prohibit the use of a substitute where EPA has determined that there are other available substitutes that pose less overall risk to human health and the environment. Thus, EPA's Significant New Alternatives Policy (SNAP) program, which implements section 612, does not provide a static list of alternatives but instead evolves the list as the EPA makes decisions informed by our overall understanding of the environmental and human health impacts as well as our current knowledge about available substitutes. In the more than twenty vears since the initial SNAP rule was promulgated, EPA has modified the SNAP lists many times, most often by expanding the list of acceptable substitutes, but in some cases by prohibiting the use of substitutes previously listed as acceptable. Where EPA is determining whether to add a new substitute to the list, EPA compares the risk posed by that new substitute to the risks posed by other alternatives on the list and determines whether that specific new substitute poses more risk than already-listed alternatives for the same use. As the lists have expanded, EPA has not reviewed the lists in a broader manner to determine whether substitutes added to the lists early in the program pose more risk than substitutes that have more recently been added. EPA is now beginning this process.

Global warming potential (GWP) is one of several criteria EPA considers in the overall evaluation of the alternatives under the SNAP program. The President's June 2013 Climate Action Plan (CAP) states that, "to reduce emissions of HFCs, the United States can and will lead both through international diplomacy as well as domestic actions." Furthermore, the CAP states that EPA will "use its authority through the Significant New Alternatives Policy Program to encourage private sector investment in low-emissions technology by identifying and approving climate-friendly chemicals while prohibiting certain uses of the most harmful chemical alternatives." In our first effort to take a broader look at the SNAP lists, we have focused on those listed substitutes that have a high GWP relative to other alternatives in specific end-uses. In determining whether to change the status of these substitutes for particular end-uses, we performed a full comparative risk analysis, based on our criteria for review, with other available alternatives also listed as acceptable for these end-uses.

In an August 6, 2014, Federal Register Notice of Proposed Rulemaking (79 FR 46126), the U.S. Environmental Protection Agency (hereafter referred to as EPA or the Agency) proposed to change the status of certain substitutes 1 that at that time were listed as acceptable under the SNAP program. After reviewing public comments and available information, in today's action, EPA is modifying the listings from acceptable to unacceptable; acceptable, subject to use conditions; or acceptable, subject to narrowed use limits for certain hydrofluorocarbons (HFCs) and HFC blends in various end-uses in the aerosols, foam blowing, and refrigeration and air conditioning sectors where other alternatives are available or potentially available that pose lower overall risk to human health and the environment. Per the guiding principles of the SNAP program, this action does not specify that any HFCs are unacceptable across all sectors and end-uses. Instead, in all cases, EPA considered the intersection between the specific HFC or HFC blend and the particular end-use and the availability of substitutes for those particular enduses. EPA is also not specifying that, for any sector, the only acceptable substitutes are HFC-free. EPA recognizes that both fluorinated (e.g., HFCs, hydrofluoroolefins (HFOs)) and nonfluorinated (e.g., hydrocarbons (HCs)

 $<sup>^{\</sup>rm 1}{\rm The\; terms\; ``substitutes''}$  and ``alternatives'' are used interchangeably.

and carbon dioxide (CO<sub>2</sub>)) substitutes may pose lower overall risk to human health and the environment, depending on the particular use. Instead, consistent with CAA section 612 as we have historically interpreted it under the SNAP program, EPA is making these modifications based on our evaluation of the substitutes addressed in this action using the SNAP criteria for evaluation and considering the current suite of other available and potentially available substitutes.

On that basis, EPA is modifying the following listings by sector and end-use as of the dates indicated. EPA will continue to monitor the development and deployment of other alternatives as well as their uptake by industries affected by today's action. If EPA receives new information indicating that other alternatives will not be available by the change of status dates specified, EPA may propose further action to adjust the relevant dates.

#### (1) Aerosols

• EPA is listing HFC-125 as unacceptable for use as an aerosol propellant as of January 1, 2016.

- EPA is listing HFC-134a, HFC-227ea, and blends of HFC-134a and HFC-227ea as unacceptable for use as aerosol propellants as of July 20, 2016, except for those uses specifically listed as acceptable, subject to use conditions.
- EPA is listing HFC–227ea and blends of HFC–134a and HFC–227ea as acceptable, subject to use conditions, as of July 20, 2016, for use in metered dose inhalers (MDIs) approved by the U.S. Food and Drug Administration (FDA).
- EPA is listing HFC–134a as acceptable, subject to use conditions, as of July 20, 2016, until January 1, 2018, for the following specific uses:
- o products for which new formulations require federal governmental review, including: EPA pesticide registration, military or space agency specifications, or FDA approval (aside from MDIs); and
- products for smoke detector functionality testing.
- EPA is listing HFC-134a as acceptable, subject to use conditions, as of July 20, 2016, for the following specific uses:
- cleaning products for removal of grease, flux and other soils from electrical equipment or electronics;
  - refrigerant flushes;
- products for sensitivity testing of smoke detectors;
- sprays containing corrosion preventive compounds used in the maintenance of aircraft, electrical equipment or electronics, or military equipment;

- duster sprays specifically for removal of dust from photographic negatives, semiconductor chips, and specimens under electron microscopes or for use on energized electrical equipment;
- adhesives and sealants in large canisters;
- lubricants and freeze sprays for electrical equipment or electronics;
  - sprays for aircraft maintenance;
- pesticides for use near electrical wires or in aircraft, in total release insecticide foggers, or in certified organic use pesticides for which EPA has specifically disallowed all other lower-GWP propellants;
- o mold release agents and mold cleaners;
- lubricants and cleaners for spinnerettes for synthetic fabrics;
- document preservation sprays;
   MDIs approved by the FDA for medical purposes;
  - wound care sprays;
- o topical coolant sprays for pain relief; and
- oproducts for removing bandage adhesives from skin.

(2) Refrigeration and air conditioning sector; Motor vehicle air conditioning (MVAC) systems for newly manufactured light-duty vehicles

EPA is listing HFC–134a as unacceptable for newly manufactured light-duty motor vehicles beginning in Model Year (MY) 2021 except as allowed under a narrowed use limit for use in newly manufactured light-duty vehicles destined for use in countries that do not have infrastructure in place for servicing with other acceptable refrigerants. This narrowed use limit will be in place through MY 2025. Beginning in MY 2026, HFC-134a will be unacceptable for use in all newly manufactured light-duty vehicles. EPA is also listing the use of certain refrigerant blends as unacceptable in newly manufactured light-duty motor vehicles starting with MY 2017.

(3) Refrigeration and air conditioning sector; Retail food refrigeration and vending machines

EPA is listing a number of refrigerants as unacceptable in a number of retail food refrigeration categories and in the vending machines end-use, as follows:

- Retrofitted supermarket systems: R–404A, R–407B, R–421B, R–422A, R–422C, R–422D, R–428A, R–434A, and R–507A as of July 20, 2016
- New supermarket systems: HFC– 227ea, R–404A, R–407B, R–421B, R– 422A, R–422C, R–422D, R–428A, R– 434A, and R–507A as of January 1, 2017
- Retrofitted remote condensing units: R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, and R-507A as of July 20, 2016

- New remote condensing units: HFC-227ea, R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, and R-507A as of January 1, 2018
- Retrofitted vending machines: R– 404A and R–507A as of July 20, 2016
- New vending machines: FOR12A, FOR12B, HFC–134a, KDD6, R–125/290/134a/600a (55.0/1.0/42.5/1.5), R–404A, R–407C, R–410A, R–410B, R–417A, R–421A, R–422B, R–422C, R–422D, R–426A, R–437A, R–438A, R–507A, RS–24 (2002 formulation), and SP34E as of January 1, 2019
- Retrofitted stand-alone retail food refrigeration equipment: R–404A and R– 507A as of July 20, 2016
- New stand-alone medium-temperature units with a compressor capacity below 2,200 Btu/hr and not containing a flooded evaporator: FOR12A, FOR12B, HFC–134a, HFC–227ea, KDD6, R–125/290/134a/600a (55.0/1.0/42.5/1.5), R–404A, R–407A, R–407B, R–407C, R–407F, R–410A, R–410B, R–417A, R–421A, R–421B, R–422A, R–422B, R–422C, R–422D, R–424A, R–426A, R–428A, R–434A, R–437A, R–438A, R–507A, RS–24 (2002 formulation), RS–44 (2003 formulation), SP34E, and THR–03 as of January 1, 2019
- · New stand-alone mediumtemperature units with a compressor capacity equal to or greater than 2,200 Btu/hr and stand-alone mediumtemperature units containing a flooded evaporator: FOR12A, FOR12B, HFC-134a, HFC-227ea, KDD6, R-125/290/ 134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-426A, R-428A, R-434A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, and THR-03 as of January 1, 2020
- New stand-alone low-temperature units: HFC-227ea, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-436A, R-436A, R-436A, R-436A, R-437A, R-436A, R-507A, and RS-44 (2003 formulation) as of January 1, 2020

We are also providing clarification on several questions identified during the comment period. Specifically, we are providing clarification of the terms we are using for the various end-use categories covered by this rule, including "supermarket systems," "remote condensing units," and "standalone equipment." We are also providing clarification on certain types of equipment that do not fall within the categories and end-uses covered by this

rule, including blast chillers, certain ice makers, very-low temperature refrigeration equipment, and equipment that dispenses chilled beverage or food (e.g., soft-serve ice cream) via a nozzle. Finally, we are also providing clarification regarding our use of the terms "new" and "retrofit" and how those terms relate to service of existing equipment.

(4) Foams

EPA is listing a number of foam blowing agents unacceptable in each foams end-use excluding rigid PU spray foam, except as allowed under a narrowed use limit for military or spaceand aeronautics-related applications. For military or space- and aeronauticsrelated applications, we are changing the listing status to acceptable, subject to a narrowed use limit, as of the status change date for the remainder of each end-use (January 1 of 2017, 2019, 2020) or 2021) and then to unacceptable as of January 1, 2022. We are not taking final action on rigid PU spray foam at this time. The unacceptable listing for all other end-uses is as follows:

- Rigid polyurethane (PU) appliance foam: HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6, as of January 1, 2020
- Rigid PU commercial refrigeration and sandwich panels: HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6, as of January 1, 2020
- Rigid PU slabstock and other: HFC– 134a, HFC–245fa, HFC–365mfc and blends thereof; Formacel TI, and Formacel Z–6, as of January 1, 2019
- Rigid PU and polyisocyanurate laminated boardstock: HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; as of January 1, 2017

• Flexible PU: HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; as of January 1, 2017

• Integral skin PU: HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof; Formacel TI, and Formacel Z–6, as of

January 1, 2017

- Polystyrene extruded sheet: HFC–134a, HFC–245fa, HFC–365mfc, and blends thereof; Formacel TI, and Formacel Z–6, as of January 1, 2017
- Polystyrene extruded boardstock and billet (XPS): HFC-134a, HFC-245fa,

HFC–365mfc, and blends thereof; Formacel TI, Formacel B, and Formacel Z–6, as of January 1, 2021

- Polyolefin: HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6, as of January 1, 2020
- Phenolic insulation board and bunstock: HFC-143a, HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; as of January 1, 2017
- Rigid PU marine flotation foam: HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6, as of January 1, 2020

While EPA proposed and requested comments on interpreting the SNAP unacceptability determinations to apply to the import of foam products that retain the blowing agents (*i.e.*, closed cell foams), EPA is not finalizing that change in this rulemaking.

(5) Hydrochlorofluorocarbons (HCFCs)

As proposed, EPA is also modifying the listings for HCFC-141b, HCFC-142b, and HCFC-22, as well as blends that contain these substances in aerosols, foam blowing agents, fire suppression and explosion protection agents, sterilants, and adhesives, coatings and inks. These modifications align the SNAP listings with other parts of the stratospheric protection program, specifically section 605 and the implementing regulations at 40 CFR part 82 subpart A and section 610 and the implementing regulations at 40 CFR part 82 subpart C. The modified listings will apply 60 days following publication of this final rule.

(6) Overview of public comments EPA received over 7,500 comments on the proposed rule. EPA requested and received comments on the proposed listing decisions as well as the proposed change of status dates. As noted in response to comments throughout this document, the decision on modifying each listing is based on the SNAP program's comparative risk framework. This includes information concerning whether there are alternatives available with lower overall risk to human health and the environment for the end-uses considered. As part of our consideration of the availability of those alternatives, we considered all available information,

including information provided during the public comment period, and information claimed as confidential and provided during meetings, regarding technical challenges that may affect the time at which the alternatives can be used safely and used consistent with other requirements such as testing and code compliance obligations. We grouped comments together and responded to the issues raised by the comments in the sections that follow, or in a separate response to comments document which is included in the docket for this rule (EPA, 2015a). This final rule reflects some changes to our proposal, based on information and data received during the public comment period.

The sections that follow describe EPA's final action for each of the three sectors covered in this rulemakingaerosols; foam blowing; and refrigeration and air-conditioning, including commercial refrigeration and motor vehicle air conditioning. For the end-uses addressed within each sector we explain the change of status determination and the dates when the change of status will apply. EPA has updated documentation for this rule including market characterizations, analyses of costs associated with sector transitions, estimated benefits associated with the transition to other alternatives, and potential small business impacts. 23456789101112 These documents are available in the docket. EPA provided separate market characterizations by sector for the proposed rule but is providing a single document consolidating this information, and updated to reflect information received during the public comment period, for this final action. The emissions avoided from this final rule are estimated to be 26 to 31 million metric tons of carbon dioxide equivalent (MMTCO<sub>2</sub>eq) in 2020. The avoided emissions are estimated to be 54 to 64 MMTCO<sub>2</sub>eq in 2025 and 78 to 101 MMTCO<sub>2</sub>eq in 2030 (EPA, 2015b).

#### B. Does this action apply to me?

Potential entities that may be affected by this final rule include:

 $<sup>^2</sup>$  ICF, 2014a. Market Characterization of the U.S. Aerosols Industry. May 2014.

 $<sup>^3</sup>$  ICF, 2014b. Market Characterization of the U.S. Foams Industry. May 2014.

<sup>&</sup>lt;sup>4</sup>ICF, 2014c. Market Characterization of the U.S. Commercial Refrigeration Industry. May 2014.

<sup>&</sup>lt;sup>5</sup> ICF, 2014d. Market Characterization of the Motor Vehicle Air Conditioning Industry. May 2014.

<sup>&</sup>lt;sup>6</sup> ICF, 2014f. Economic Impact Screening Analysis for Regulatory Options To Change Listing Status of High-GWP Alternatives. June 2014.

<sup>&</sup>lt;sup>7</sup> EPA, 2014a. Climate Benefits of the SNAP Program Status Change Rule. June 2014.

<sup>&</sup>lt;sup>8</sup> ICF, 2014g. Revised Preliminary Cost Analysis for Regulatory Options To Change Listing Status of High-GWP Alternatives. June 2014.

<sup>&</sup>lt;sup>9</sup> ICF, 2015a. Market Characterization of the U.S. Motor Vehicle Air Conditioning Industry, U.S.

Foams Industry, U.S. Aerosols Industry, and U.S. Commercial Refrigeration Industry. July 2015

<sup>&</sup>lt;sup>10</sup> ICF, 2015b. Economic Impact Screening Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives—Revised. July 2015.

<sup>&</sup>lt;sup>11</sup> EPA, 2015b. Climate Benefits of the SNAP Program Status Change Rule. July 2015.

<sup>&</sup>lt;sup>12</sup>ICF, 2015c. Revised Cost Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives. July 2015.

TABLE 1—POTENTIALLY REGULATED ENTITIES BY NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) CODE

Category	NAICS Code	Description of regulated entities
Industry	238220	Plumbing, Heating, and Air Conditioning Contractors.
Industry	324191	Petroleum Lubricating Oil and Grease Manufacturing.
Industry	325199	All Other Basic Organic Chemical Manufacturing.
Industry	325412	Pharmaceutical Preparation Manufacturing.
Industry	325510	Paint and Coating Manufacturing.
Industry	325520	Adhesive Manufacturing.
Industry	325612	Polishes and Other Sanitation Goods.
Industry	325620	Toilet Preparation Manufacturing.
Industry	325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing.
Industry	326140	Polystyrene Foam Product Manufacturing.
Industry	326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing.
Industry	333415	Air Conditioning and Warm Air Heating Equipment and Commercial and Industrial
•		Refrigeration Equipment Manufacturing.
Industry	336211	Motor Vehicle Body Manufacturing.
Industry	3363	Motor Vehicle Parts Manufacturing.
Industry	336611	Ship Building and Repairing.
Industry	336612	Boat Building.
Industry	339113	Surgical Appliance and Supplies Manufacturing.
Retail	423620	Household Appliances, Electric Housewares, and Consumer Electronics Merchant
		Wholesalers.
Retail	423740	Refrigeration Equipment and Supplies Merchant Wholesalers.
Retail	44511	Supermarkets and Other Grocery (except Convenience) Stores.
Retail	445110	Supermarkets and Other Grocery (except Convenience) Stores.
Retail	445120	Convenience Stores.
Retail	44521	Meat Markets.
Retail	44522	Fish and Seafood Markets.
Retail	44523	Fruit and Vegetable Markets.
Retail	445291	Baked Goods Stores.
Retail	445292	Confectionary and Nut Stores.
Retail	445299	All Other Specialty Food Stores.
Retail	4453	Beer, Wine, and Liquor Stores.
Retail	446110	Pharmacies and Drug Stores.
Retail	44711	Gasoline Stations with Convenience Stores.
Retail	452910	Warehouse Clubs and Supercenters.
Retail	452990	All Other General Merchandise Stores.
Services	72111	Hotels (except Casino Hotels) and Motels.
Services	72112	Casino Hotels.
Retail	72241	Drinking Places (Alcoholic Beverages).
Retail	722513	Limited-Service Restaurants.
Retail	722514	Cafeterias, Grill Buffets, and Buffets.
Retail	722515	Snack and Nonalcoholic Beverage Bars

This table is not intended to be exhaustive, but rather a guide regarding entities likely to use the substitute whose use is regulated by this action. If you have any questions about whether this action applies to a particular entity, consult the person listed in the above section, FOR FURTHER INFORMATION CONTACT.

C. What acronyms and abbreviations are used in the preamble?

Below is a list of acronyms and abbreviations used in the preamble of this document:

AAM—Alliance of Automobile Manufacturers

ACGIH—American Conference of Governmental Industrial Hygienists AGC—Asahi Glass Company

AHAM—Association of Home Appliance Manufacturers

AHRI— Air-Conditioning, Heating, and Refrigeration Institute

AIHA—American Industrial Hygiene Association

The Alliance—Alliance for Responsible Atmospheric Policy

ARPI—Automotive Refrigeration Products Institute

ASHRAE—American Society of Heating, Refrigerating and Air-Conditioning Engineers

CAA—Clean Air Act

CAP—Climate Action Plan

CARB—California Air Resource Board

CAS Reg. No.—Chemical Abstracts Service Registry Identification Number

CBI—Confidential Business Information CFC—Chlorofluorocarbon

CFESA—Commercial Food Equipment Service Association

CFR—Code of Federal Regulations

CH₄—Methane

CO<sub>2</sub>—Carbon Dioxide

CO2eq-Carbon dioxide equivalent

CRA—Congressional Review Act

CSPA—Consumer Specialty Products Association

DME—Dimethyl ether

DoD—United States Department of Defense DOE—United States Department of Energy

DX—Direct expansion

EIA-Environmental Investigation Agency-US

EO—Executive Order

EPA—United States Environmental

Protection Agency EU—European Union

FDA—United States Food and Drug

Administration

FM—Factory Mutual

FMI—Food Marketing Institute

FR—Federal Register

GHG—Greenhouse Gas

Global Automakers—Association of Global Automakers

GWP—Global Warming Potential

HC—Hydrocarbon

HCFC—Hydrochlorofluorocarbon

HFC-Hydrofluorocarbon

HFO—Hydrofluoroolefin

ICF—ICF International, Inc.

IGSD-Institute for Governance and

Sustainable Development

IPAC—International Pharmaceutical Aerosol Consortium

IPCC—Intergovernmental Panel on Climate

Change LCCP—Life Cycle Climate Performance

LD GHG-Light-Duty Greenhouse Gas

MAC Directive—Directive on Mobile Air Conditioning MDI-Metered Dose Inhaler Mexichem—Mexichem Fluor, Inc. MMTCO2eq—Million Metric Tons of Carbon Dioxide equivalent MVAC—Motor vehicle air conditioning MY—Model Year N<sub>2</sub>—Nitrogen  $N_2O$ —Nitrous Oxide NAA—National Aerosol Association NADA—National Automobile Dealers Association NAICS—North American Industrial Classification System NAFEM-North American Association of Food Equipment Manufacturers NAM-National Association of Manufacturers NAMA—National Automatic Merchandising Association NASA—National Aeronautics and Space Administration NFPA—National Fire Protection Association NHTSA—National Highway Traffic Safety Administration NIOSH-United States National Institute for Occupational Safety and Health NMMA—National Marine Manufacturers Association NPRM—Notice of proposed rulemaking NRA—National Restaurant Association NRDC—Natural Resources Defense Council NSF-National Sanitation Foundation NTTAA-National Technology Transfer and Advancement Act OEM—Original Equipment Manufacturer ODP—Ozone Depletion Potential ODS—Ozone-depleting Substance OMB-United States Office of Management and Budget OSHA—United States Occupational Safety and Health Administration PEL—Permissible Exposure Limit PFC—Perfluorocarbons *PU*—Polyurethane RCRA—Resource Conservation and Recovery REACH—Registration, Evaluation, Authorization and Restriction of Chemicals RfC—Reference Concentration RRR—Recovery, Recycling and Recharging RSC—Radiator Specialty Company RSES—Refrigeration Service Engineers Society SIP—State Implementation Plan SAE ICCC—SAE International's Interior Climate Control Committee SF<sub>6</sub>—Sulfur Hexafluoride SBREFA—Small Business Regulatory Enforcement Fairness Act SISNOSE-Significant impact on a substantial number of small entities SNAP—Significant New Alternatives Policy SRES—Special Report on Emissions Scenarios TEAP—Technical and Economic Assessment Panel TEWI-Total Equivalent Warming Impact TLV—Threshold Limit Value TXV—Thermostatic Expansion Valve UL—Underwriters Laboratories, Inc. UMRA—Unfunded Mandates Reform Act UNEP-United Nations Environmental

Programme

VOC-Volatile Organic Compounds

WEEL—Workplace Environmental Exposure Limit

XPS—Extruded Polystyrene Boardstock and Billet

XPSA—Extruded Polystyrene Association

#### II. How does the SNAP program work?

A. What are the statutory requirements and authority for the SNAP program?

CAA section 612 requires EPA to develop a program for evaluating alternatives to ozone-depleting substances (ODS). This program is known as the SNAP program. The major provisions of section 612 are:

#### 1. Rulemaking

Section 612(c) requires EPA to promulgate rules making it unlawful to replace any class I (chlorofluorocarbon, halon, carbon tetrachloride, methyl chloroform, methyl bromide, hydrobromofluorocarbon, and chlorobromomethane) or class II (HCFC) substance with any substitute that the Administrator determines may present adverse effects to human health or the environment where the Administrator has identified an alternative that (1) reduces the overall risk to human health and the environment and (2) is currently or potentially available.

### 2. Listing of Unacceptable/Acceptable Substitutes

Section 612(c) requires EPA to publish a list of the substitutes that it finds to be unacceptable for specific uses and to publish a corresponding list of acceptable substitutes for specific uses. The list of "acceptable" substitutes is found at <a href="https://www.epa.gov/ozone/snap/lists">www.epa.gov/ozone/snap/lists</a> and the lists of "unacceptable," "acceptable subject to use conditions," and "acceptable subject to narrowed use limits" substitutes are found in the appendices to 40 CFR part 82 subpart G.

#### 3. Petition Process

Section 612(d) grants the right to any person to petition EPA to add a substance to, or delete a substance from, the lists published in accordance with section 612(c). The Agency has 90 days to grant or deny a petition. Where the Agency grants the petition, EPA must publish the revised lists within an additional six months.

#### 4. 90-Day Notification

Section 612(e) directs EPA to require any person who produces a chemical substitute for a class I substance to notify the Agency not less than 90 days before new or existing chemicals are introduced into interstate commerce for significant new uses as substitutes for a class I substance. The producer must also provide the Agency with the producer's unpublished health and safety studies on such substitutes.

#### 5. Outreach

Section 612(b)(1) states that the Administrator shall seek to maximize the use of federal research facilities and resources to assist users of class I and II substances in identifying and developing alternatives to the use of such substances in key commercial applications.

#### 6. Clearinghouse

Section 612(b)(4) requires the Agency to set up a public clearinghouse of alternative chemicals, product substitutes, and alternative manufacturing processes that are available for products and manufacturing processes which use class I and II substances.

### B. What are EPA's regulations implementing CAA section 612?

On March 18, 1994, EPA published the initial SNAP rule (59 FR 13044) which established the process for administering the SNAP program and issued EPA's first lists identifying acceptable and unacceptable substitutes in major industrial use sectors (40 CFR part 82, subpart G). These sectors are the following: Refrigeration and air conditioning; foam blowing; solvents cleaning; fire suppression and explosion protection; sterilants; aerosols; adhesives, coatings and inks; and tobacco expansion. These sectors comprise the principal industrial sectors that historically consumed the largest volumes of ODS.

### C. How do the regulations for the SNAP program work?

Under the SNAP regulations, anyone who produces a substitute to replace a class I or II ODS in one of the eight major industrial use sectors must provide the Agency with notice and the required health and safety information on the substitute at least 90 days before introducing it into interstate commerce for significant new use as an alternative. 40 CFR 82.176(a). While this requirement typically applies to chemical manufacturers as the person likely to be planning to introduce the substitute into interstate commerce, <sup>13</sup> it

Continued

<sup>&</sup>lt;sup>13</sup> As defined at 40 CFR 82.104 "interstate commerce" means the distribution or transportation of any product between one state, territory, possession or the District of Columbia, and another state, territory, possession or the District of Columbia, or the sale, use or manufacture of any product in more than one state, territory, possession or District of Columbia. The entry points for which a product is introduced into interstate commerce are the release of a product from the facility in

may also apply to importers, formulators, equipment manufacturers, or end users <sup>14</sup> when they are responsible for introducing a substitute into commerce. The 90-day SNAP review process begins once EPA receives the submission and determines that the submission includes complete and adequate data. 40 CFR 82.180(a). The CAA and the SNAP regulations, 40 CFR 82.174(a), prohibit use of a substitute earlier than 90 days after a complete submission has been provided to the Agency.

The Agency has identified four possible decision categories for substitute submissions: Acceptable; acceptable, subject to use conditions; acceptable, subject to narrowed use limits; and unacceptable.15 40 CFR 82.180(b). Use conditions and narrowed use limits are both considered "use restrictions" and are explained below. Substitutes that are deemed acceptable without use conditions can be used for all applications within the relevant enduses within the sector and without limits under SNAP on how they may be used. Substitutes that are acceptable subject to use restrictions may be used only in accordance with those restrictions. Substitutes that are found to be unacceptable may not be used after the date specified in the rulemaking adding such substitute to the list of unacceptable substitutes.16

After reviewing a substitute, the Agency may determine that a substitute is acceptable only if certain conditions in the way that the substitute is used are met to ensure risks to human health and the environment are not significantly greater than other available substitutes. EPA describes such substitutes as "acceptable subject to use conditions." Entities that use these substitutes without meeting the associated use

which the product was manufactured, the entry into a warehouse from which the domestic manufacturer releases the product for sale or distribution, and at the site of United States Customs clearance.

conditions are in violation of section 612 of the CAA and EPA's SNAP regulations. 40 CFR 82.174(c).

For some substitutes, the Agency may permit a narrow range of use within an end-use or sector. For example, the Agency may limit the use of a substitute to certain end-uses or specific applications within an industry sector. The Agency requires a user of a narrowed use substitute to demonstrate that no other acceptable substitutes are available for their specific application. EPA describes these substitutes as "acceptable subject to narrowed use limits." A person using a substitute that is acceptable subject to narrowed use limits in applications and end-uses that are not consistent with the narrowed use limit is using these substitutes in violation of section 612 of the CAA and EPA's SNAP regulations. 40 CFR 82.174(c).

The section 612 mandate for EPA to prohibit the use of a substitute that may present risk to human health or the environment where a lower risk alternative is available or potentially available 17 provides EPA with the authority to change the listing status of a particular substitute if such a change is justified by new information or changed circumstance. The Agency publishes its SNAP program decisions in the **Federal Register**. EPA uses notice-and-comment rulemaking to place any alternative on the list of prohibited substitutes, to list a substitute as acceptable only subject to use conditions or narrowed use limits, or to remove a substitute from either the list of prohibited or acceptable substitutes.

In contrast, EPA publishes "notices of acceptability" to notify the public of substitutes that are deemed acceptable with no restrictions. As described in the preamble to the rule initially implementing the SNAP program (59 FR 13044; March 18, 1994), EPA does not believe that rulemaking procedures are necessary to list substitutes that are acceptable without restrictions because such listings neither impose any sanction nor prevent anyone from using a substitute.

Many SNAP listings include "comments" or "further information" to

provide additional information on substitutes. Since this additional information is not part of the regulatory decision, these statements are not binding for use of the substitute under the SNAP program. However, regulatory requirements so listed are binding under other regulatory programs (e.g., worker protection regulations promulgated by the U.S. Occupational Safety and Health Administration (OSHA)). The "further information" classification does not necessarily include all other legal obligations pertaining to the use of the substitute. While the items listed are not legally binding under the SNAP program, EPA encourages users of substitutes to apply all statements in the "further information" column in their use of these substitutes. In many instances, the information simply refers to sound operating practices that have already been identified in existing industry and/or building codes or standards. Thus, many of the statements, if adopted, would not require the affected user to make significant changes in existing operating practices.

D. What are the guiding principles of the SNAP program?

The seven guiding principles of the SNAP program, elaborated in the preamble to the initial SNAP rule and consistent with section 612, are discussed below.

• Evaluate substitutes within a comparative risk framework

The SNAP program evaluates the risk of alternative compounds compared to available or potentially available substitutes to the ozone depleting compounds which they are intended to replace. The risk factors that are considered include ozone depletion potential as well as flammability, toxicity, occupational health and safety, and contributions to climate change and other environmental factors.

• Do not require that substitutes be risk free to be found acceptable

Substitutes found to be acceptable must not pose significantly greater risk than other substitutes, but they do not have to be risk free. A key goal of the SNAP program is to promote the use of substitutes that minimize risks to human health and the environment relative to other alternatives. In some cases, this approach may involve designating a substitute acceptable even though the compound may pose a risk of some type, provided its use does not pose significantly greater risk than other alternatives.

• Restrict those substitutes that are significantly worse

<sup>&</sup>lt;sup>14</sup> As defined at 40 CFR 82.172 "end-use" means processes or classes of specific applications within major industrial sectors where a substitute is used to replace an ozone-depleting substance.

<sup>&</sup>lt;sup>15</sup>The SNAP regulations also include "pending," referring to submissions for which EPA has not reached a determination, under this provision.

<sup>&</sup>lt;sup>16</sup> As defined at 40 CFR 82.172, "use" means any use of a substitute for a Class I or Class II ozone-depleting compound, including but not limited to use in a manufacturing process or product, in consumption by the end-user, or in intermediate uses, such as formulation or packaging for other subsequent uses. This definition of use encompasses manufacturing process of products both for domestic use and for export. Substitutes manufactured within the United States exclusively for export are subject to SNAP requirements since the definition of use in the rule includes use in the manufacturing process, which occurs within the United States.

<sup>&</sup>lt;sup>17</sup> In addition to acceptable commercially available substitutes, the SNAP program may consider potentially available substitutes. The SNAP program's definition of "potentially available "is "any alternative for which adequate health, safety, and environmental data, as required for the SNAP notification process, exist to make a determination of acceptability, and which the Agency reasonably believes to be technically feasible, even if not all testing has yet been completed and the alternative is not yet produced or sold." (40 CFR 82.172)

EPA does not intend to restrict a substitute if it has only marginally greater risk. Drawing fine distinctions would be extremely difficult. The Agency also does not want to intercede in the market's choice of substitutes by listing as unacceptable all but a few substitutes for each end-use, and does not intend to do so unless a substitute has been proposed or is being used that is clearly more harmful to human health or the environment than other available or potentially available alternatives.

 Evaluate risks by use Central to SNAP's evaluations is the intersection between the characteristics of the substitute itself and its specific end-use application. Section 612 requires that substitutes be evaluated by use. Environmental and human health exposures can vary significantly depending on the particular application of a substitute. Thus, the risk characterizations must be designed to represent differences in the environmental and human health effects associated with diverse uses. This approach cannot, however, imply fundamental tradeoffs with respect to different types of risk to either the environment or to human health.

 Provide the regulated community with information as soon as possible

The Agency recognizes the need to provide the regulated community with information on the acceptability of various substitutes as soon as possible. To do so, EPA issues notices or determinations of acceptability and rules identifying substitutes as unacceptable, acceptable to use conditions or acceptable subject to narrowed use limits in the Federal Register. In addition, we maintain lists of acceptable and unacceptable alternatives on our Web site, www.epa.gov/ozone/snap.

• Do not endorse products manufactured by specific companies

The Agency does not issue companyspecific product endorsements. In many cases, the Agency may base its analysis on data received on individual products, but the addition of a substitute to the acceptable list based on that analysis does not represent an endorsement of that company's products.

• Defer to other environmental regulations when warranted

In some cases, EPA and other federal agencies have developed extensive regulations under other sections of the CAA or other statutes that address potential environmental or human health effects that may result from the use of alternatives to class I and class II substances. For example, use of some substitutes may in some cases entail

increased use of chemicals that contribute to tropospheric air pollution. The SNAP program takes existing regulations under other programs into account when reviewing substitutes.

E. What are EPA's criteria for evaluating substitutes under the SNAP program?

EPA applies the same criteria for determining whether a substitute is acceptable or unacceptable. These criteria, which can be found at § 82.180(a)(7), include atmospheric effects and related health and environmental effects, ecosystem risks, consumer risks, flammability, and cost and availability of the substitute. To enable EPA to assess these criteria, we require submitters to include various information including ozone depletion potential (ODP), GWP, toxicity flammability, and the potential for human exposure.

When evaluating potential substitutes, EPA evaluates these criteria in the following groupings:

- Atmospheric effects—The SNAP program evaluates the potential contributions to both ozone depletion and climate change. The SNAP program considers the ozone depletion potential and the 100-year integrated GWP of compounds to assess atmospheric effects.
- Exposure assessments—The SNAP program uses exposure assessments to estimate concentration levels of substitutes to which workers, consumers, the general population, and the environment may be exposed over a determined period of time. These assessments are based on personal monitoring data or area sampling data if available. Exposure assessments may be conducted for many types of releases including:
- (1) Releases in the workplace and in
- (2) Releases to ambient air and surface water;
- (3) Releases from the management of solid wastes.
- Toxicity data—The SNAP program uses toxicity data to assess the possible health and environmental effects of exposure to substitutes. We use broad health-based criteria such as:
- (1) Permissible Exposure Limits (PELs) for occupational exposure;
- (2) Inhalation reference concentrations (RfCs) for noncarcinogenic effects on the general population;
- (3) Cancer slope factors for carcinogenic risk to members of the general population.

When considering risks in the workplace, if OSHA has not issued a PEL for a compound, EPA then

considers Recommended Exposure Limits from the National Institute for Occupational Safety and Health (NIOSH), Workplace Environmental Exposure Limits (WEELs) set by the American Industrial Hygiene Association (AIHA), or threshold limit values (TLVs) set by the American Conference of Governmental Industrial Hygienists (ACGIH). If limits for occupational exposure or exposure to the general population are not already established, then EPA derives these values following the Agency's peer reviewed guidelines. Exposure information is combined with toxicity information to explore any basis for concern. Toxicity data are used with existing EPA guidelines to develop health-based limits for interim use in these risk characterizations.

• Flammability—The SNAP program examines flammability as a safety concern for workers and consumers. EPA assesses flammability risk using

(1) Flash point and flammability limits (e.g. American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) flammability/ combustibility classifications);

(2) Data on testing of blends with

flammable components;

(3) Test data on flammability in consumer applications conducted by independent laboratories; and

(4) Information on flammability risk mitigation techniques.

• Other environmental impacts—The SNAP program also examines other potential environmental impacts like ecotoxicity and local air quality impacts. A compound that is likely to be discharged to water may be evaluated for impacts on aquatic life. Some substitutes are volatile organic compounds (VOC). EPA also notes whenever a potential substitute is considered a hazardous or toxic air pollutant (under CAA sections 112(b) and 202(l)) or hazardous waste under the Resource Conservation and Recovery Act (RCRA) subtitle C regulations.

Over the past twenty years, the menu of substitutes has become much broader and a great deal of new information has been developed on many substitutes. Because the overall goal of the SNAP program is to ensure that substitutes listed as acceptable do not pose significantly greater risk to human health and the environment than other available substitutes, the SNAP criteria should be informed by our current overall understanding of environmental and human health impacts and our experience with and current knowledge about available and potentially available substitutes. Over time, the range of substitutes reviewed by SNAP has changed, and, at the same time, scientific approaches have evolved to more accurately assess the potential environmental and human health impacts of these chemicals and alternative technologies.

### F. How are SNAP determinations updated?

Three mechanisms exist for modifying the list of SNAP determinations. First, under section 612(d), the Agency must review and either grant or deny petitions to add or delete substances from the SNAP list of acceptable or unacceptable substitutes. That provision allows any person to petition the Administrator to add a substance to the list of acceptable or unacceptable substitutes or to remove a substance from either list. The second means is through the notifications which must be submitted to EPA 90 days before introduction of a substitute into interstate commerce for significant new use as an alternative to a class I or class II substance. These 90-day notifications are required by section 612(e) of the CAA for producers of substitutes to class I substances for new uses and, in all other cases, by EPA regulations issued under sections 114 and 301 of the Act to implement section 612(c).

Finally, since the inception of the SNAP program, we have interpreted the section 612 mandate to find substitutes acceptable or unacceptable to include the authority to act on our own to add or remove a substance from the SNAP lists. In determining whether to add or remove a substance from the SNAP lists, we consider whether there are other available substitutes that pose lower overall risk to human health and the environment. In determining whether to modify a listing of a substitute we undertake the same consideration, but do so in the light of new data not considered at the time of our original listing decision, including information on new substitutes and new information on substitutes previously reviewed.

# G. What does EPA consider in deciding whether to modify the listing status of an alternative?

As described in this document and elsewhere, including in the initial SNAP rule published in the **Federal Register** on March 18, 1994 (59 FR 13044), CAA section 612 requires EPA to list as unacceptable any substitute substance where it finds that there are other substitutes currently or potentially available that reduce overall risk to human health and the environment.

The initial SNAP rule included submission requirements and presented the environmental and health risk factors that the SNAP program considers in its comparative risk framework. Environmental and human health exposures can vary significantly depending on the particular application of a substitute; therefore, EPA makes decisions based on the particular enduse where a substitute is to be used. EPA has, in many cases, found certain substitutes acceptable only for limited end-uses or subject to use restrictions.

It has now been over twenty years since the initial SNAP rule was promulgated. In that period, the menu of available alternatives has expanded greatly and now includes many substitutes with diverse characteristics and varying effects on human health and the environment. When the SNAP program began, the number of substitutes available for consideration was, for many end-uses, somewhat limited. While the SNAP program's initial comparative assessments of overall risk to human health and the environment were rigorous, often there were few substitutes upon which to apply the comparative assessment. The immediacy of the class I phaseout often meant that SNAP listed class II ODS (i.e., HCFCs) as acceptable, recognizing that they too would be phased out and were only an interim solution. Other Title VI provisions such as the section 610 Nonessential Products Ban and the section 605 Use Restriction made clear that a listing under the SNAP program could not convey permanence.

Since EPA issued the initial SNAP rule in 1994, the Agency has issued 19 rules and 30 notices that generally expand the menu of options for all SNAP sectors and end-uses.
Comparisons today apply to a broader range of options—both chemical and non-chemical—than was available at the inception of the SNAP program. Industry experience with these substitutes has also grown during the history of the program. This varies by sector and by end-use.

In addition to an expanding menu of substitutes, developments over the past 20 years have improved our understanding of global environmental issues. With regard to that information, our review of substitutes in this rule includes comparative assessments that consider our evolving understanding of a variety of factors, including climate change. GWPs and climate effects are not new elements in our evaluation framework, but as is the case with all of our review criteria, the amount and quality of information has expanded.

To the extent possible, EPA's ongoing management of the SNAP program considers new information and improved understanding of the risk to the environment and human health. EPA previously has taken several actions revising listing determinations from acceptable or acceptable with use conditions to unacceptable based on information made available to EPA after a listing was issued. For example, on January 26, 1999, EPA listed the refrigerant blend known by the trade name MT-31 as unacceptable for all refrigeration and air conditioning enduses. EPA previously listed this blend as an acceptable substitute in various enduses within the refrigeration and air conditioning sector (June 3, 1997; 62 FR 30275). Based on new information about the toxicity of one of the chemicals in the blend, EPA subsequently removed MT–31 from the list of acceptable substitutes and listed it as unacceptable in all refrigeration and air conditioning end-uses (January 26, 1999; 64 FR 3861).

Another example of EPA revising a listing determination occurred in 2007 when EPA listed HCFC-22 and HCFC-142b as unacceptable for use in the foam sector (March 28, 2007; 72 FR 14432). These HCFCs, which are ozone depleting and subject to a global production phaseout, were initially listed as acceptable substitutes since they had a lower ODP than the substances they were replacing and there were no other available substitutes that posed lower overall risk at the time of EPA's listing decision. HCFCs offered a path forward for some sectors and end-uses at a time when substitutes were far more limited. In light of the expanded availability of other substitutes with lower overall risk to human health and the environment in specific foam end-uses, and taking into account the 2010 class II ODS phasedown step, EPA changed the listing for these HCFCs in relevant end-uses from acceptable to unacceptable. In that rule, EPA noted that continued use of these HCFCs would contribute to unnecessary depletion of the ozone layer and delay the transition to substitutes that pose lower overall risk to human health and the environment. EPA established a change of status date that recognized that existing users needed time to adjust their manufacturing processes to safely accommodate the use of other substitutes.

H. Where can I get additional information about the SNAP program?

For copies of the comprehensive SNAP lists of substitutes or additional information on SNAP, refer to EPA's Web site at <a href="https://www.epa.gov/ozone/snap">www.epa.gov/ozone/snap</a>.

For more information on the Agency's process for administering the SNAP program or criteria for evaluation of substitutes, refer to the initial SNAP rule published March 18, 1994 (59 FR 13044), codified at 40 CFR part 82, subpart G. A complete chronology of SNAP decisions and the appropriate citations are found at www.epa.gov/ozone/snap/chron.html.

# III. What actions and information related to greenhouse gases have bearing on this final action to modify prior SNAP determinations?

GWP is one of several criteria EPA considers in the overall evaluation of alternatives under the SNAP program. During the past two decades, the general science on climate change and the potential contributions of greenhouse gases (GHGs) such as HFCs to climate change have become better understood.

On December 7, 2009, at 74 FR 66496, the Administrator issued two distinct findings regarding GHGs <sup>18</sup> under section 202(a) of the CAA:

- Endangerment Finding: The current and projected concentrations of the six key well-mixed greenhouse gases in the atmosphere—CO<sub>2</sub>, methane (CH<sub>4</sub>), nitrous oxide (N<sub>2</sub>O), HFCs, perfluorocarbons (PFCs), and sulfur hexafluoride (SF<sub>6</sub>)—threaten the public health and welfare of current and future generations.
- Cause or Contribute Finding: The combined emissions of these wellmixed greenhouse gases from new motor vehicles and new motor vehicle engines contribute to the greenhouse gas pollution which threatens public health and welfare.

Like the ODS they replace, HFCs are potent GHGs. <sup>19</sup> Although they represent a small fraction of the current total volume of GHG emissions, their warming impact is very strong. The most commonly used HFC is HFC–134a. HFC–134a is 1,430 times more damaging to the climate system than carbon dioxide. HFC emissions are projected to increase substantially and at an increasing rate over the next several decades if left unregulated. In the United States, emissions of HFCs are increasing more quickly than those of any other GHGs, and globally they are

increasing 10–15% annually.  $^{20}$  At that rate, emissions are projected to double by 2020 and triple by 2030.  $^{21}$  HFCs are rapidly accumulating in the atmosphere. The atmospheric concentration of HFC–134a, the most abundant HFC, has increased by about 10% per year from 2006 to 2012, and the concentrations of HFC–143a and HFC–125 have risen over 13% and 16% per year from 2007–2011, respectively.  $^{22}$   $^{23}$ 

Annual global emissions of HFCs are projected to rise to about 6.4 to 9.9 Gt CO<sub>2</sub>eq in 2050,<sup>24</sup> which is comparable to the drop in annual GHG emissions from ODS of 8.0 GtCO<sub>2</sub>eq between 1988 and 2010 (UNEP, 2011). By 2050, the buildup of HFCs in the atmosphere is projected to increase radiative forcing by up to 0.4 W m<sup>-2</sup>. This increase may be as much as one-fifth to one-quarter of the expected increase in radiative forcing due to the buildup of CO<sub>2</sub> since 2000, according to the Intergovernmental Panel on Climate Change's (IPCC's) Special Report on Emissions Scenarios (SRES) (UNEP, 2011). To appreciate the significance of the effect of projected HFC emissions within the context of all GHGs, HFCs would be equivalent to 5 to 12% of the CO2 emissions in 2050 based on the IPCC's highest CO<sub>2</sub> emissions scenario and equivalent to 27 to 69% of CO2 emissions based on the IPCC's lowest CO<sub>2</sub> emissions pathway.<sup>25</sup> <sup>26</sup> Additional information concerning the peerreviewed scientific literature and emission scenarios is available in the docket for this rulemaking.

# IV. What petitions has EPA received requesting a change in listing status for HFCs?

#### A. Summary of Petitions

EPA received three petitions requesting EPA to modify certain acceptability listings of HFC-134a and HFC-134a blends. These petitions are more fully described in the notice of proposed rulemaking (NPRM). The first petition was submitted on May 7, 2010, by Natural Resources Defense Council (NRDC) on behalf of NRDC, the Institute for Governance and Sustainable Development (IGSD), and the **Environmental Investigation Agency-US** (EIA). The petition requested that EPA remove HFC-134a from the list of acceptable substitutes in multiple enduses and move it to the list of unacceptable substitutes in those enduses. In support of their petition, the petitioners identified other substitutes that they claimed were available for use in those end-uses and they claimed these other substitutes present much lower risks to human health and environment than HFC-134a.

On February 14, 2011, EPA found the petition complete for MVAC in new passenger cars and light-duty vehicles and determined it was incomplete for other uses of HFC-134a. EPA noted in its response that, at a future date, the Agency would initiate a notice-andcomment rulemaking in response to the one complete aspect of the petition, noting in particular that EPA would evaluate and take comment on many factors, including, but not limited to, the timeframe for introduction of newer substitutes for MVAC systems into the automotive market and potential lead time for manufacturers of motor vehicles to accommodate such substitutes.

On April 26, 2012, EPA received a second petition submitted by EIA. EIA stated that, in light of the comparative nature of the SNAP program's evaluation of substitutes and given that other acceptable substitutes are on the market or soon to be available, EPA should remove HFC-134a and HFC-134a blends from the list of acceptable substitutes for uses where EPA found chlorofluorocarbons (CFCs) and HCFCs to be nonessential under section 610 of the Act. EIA also requested that the schedule for moving HFC-134a and HFC-134a blends from the list of acceptable to unacceptable substitutes be based on the "most rapidly feasible transitions to one or more of the" acceptable substitutes for each use. The petitioner noted that initial approvals of HFC-134a for a number of end-uses occurred in the 1990s and were based

<sup>&</sup>lt;sup>18</sup> The relevant scientific and technical information summarized to support the Endangerment Finding and the Cause or Contribute Finding can be found at: www.epa.gov/climatechange/Downloads/endangerment/Endangerment TSD.pdf.

<sup>&</sup>lt;sup>19</sup> IPCC/TEAP (2005) Special Report: Safeguarding the Ozone Layer and the Global Climate System: Issues Related to Hydrofluorocarbons and Perfluorocarbons (Cambridge Univ Press, New York).

 $<sup>^{20}\,\</sup>rm UNEP$  2011. HFGs: A Critical Link in Protecting Climate and the Ozone Layer. United Nations Environment Programme.

<sup>&</sup>lt;sup>21</sup> Akerman, Nancy H. Hydrofluorocarbons and Climate Change: Summaries of Recent Scientific and Papers, 2013.

<sup>&</sup>lt;sup>22</sup> Montzka, S.A.: HFCs in the Atmosphere: Concentrations, Emissions and Impacts, ASHRAE/ NIST Conference 2012.

<sup>&</sup>lt;sup>23</sup> NOAA data at ftp://ftp.cmdl.noaa.gov/hats/hfcs/.

<sup>&</sup>lt;sup>24</sup> Velders, G.J.M., D.W. Fahey, J.S. Daniel, M. McFarland, S.O. Andersen (2009) The large contribution of projected HFC emissions to future climate forcing. *Proceedings of the National Academy of Sciences USA* 106: 10949–10954.

<sup>&</sup>lt;sup>25</sup> HFCs: A Critical Link in Protecting Climate and the Ozone Layer. United Nations Environment Programme (UNEP), 2011, 36pp

<sup>&</sup>lt;sup>26</sup> IPCC, 2013: Annex II: Climate System Scenario Tables [Prather, M., G. Flato, P. Friedlingstein, C. Jones, J.-F. Lamarque, H. Liao and P. Rasch (eds.)]. In: Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change [Stocker, T.F., D. Qin, G.-K. Plattner, M. Tignor, S.K. Allen, J. Boschung, A. Nauels, Y. Xia, V. Bex and P.M. Midgley (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA.

on the assessment made then that 1) HFC–134a does not contribute to ozone depletion; 2) HFC–134a's GWP and atmospheric lifetime were close to those of other substitutes that had been determined to be acceptable for the enduses; and 3) HFC–134a is not flammable, and its toxicity is low.<sup>27</sup> The petitioner stated that the analysis used in the listing decisions may have been appropriate in the 1990s but was no longer so today given the range of other available or potentially available substitutes at present.

On August 7, 2012, EPA notified the petitioner that this petition was incomplete. EPA and the petitioner have exchanged further correspondence that can be found in the docket.

A third petition was filed on April 27, 2012, by NRDC, EIA and IGSD. They requested that EPA:

- Remove HFC–134a from the list of acceptable substitutes for CFC–12 in household refrigerators and freezers and stand-alone retail food refrigerators and freezers:
- Restrict the sales of SNAP-listed refrigerants to all except certified technicians with access to service tools required under existing EPA regulations;
- Adopt a standardized procedure to determine the speed of transition from obsolete high-GWP HFCs to nextgeneration alternatives and substitutes;
- Remove, in addition to HFC–134a, all other refrigerants with 100-year GWPs greater than 150 from the acceptable list for household refrigerators and freezers and standalone retail food refrigerators and freezers

On August 7, 2013, EPA found this petition to be incomplete. EPA and the petitioner have exchanged further correspondence that can be found in the docket.

B. How This Action Relates to the Climate Action Plan and Petitions

This action is consistent with a provision in the President's CAP announced June 2013: Moving forward, the Environmental Protection Agency will use its authority through the Significant New Alternatives Policy Program to encourage private sector investment in low-emissions technology by identifying and approving climate-friendly chemicals while prohibiting certain uses of the most harmful chemical alternatives.

The CAP further states: "to reduce emissions of HFCs, the United States can and will lead both through international diplomacy as well as domestic actions." This rule is also consistent with that call for leadership through domestic actions. As regards international leadership, for the past five years, the United States, Canada, and Mexico have proposed an amendment to the Montreal Protocol to phase down the production and consumption of HFCs. Global benefits of the amendment proposal would yield significant reductions of over 90 gigatons of carbon dioxide equivalent  $(CO_2eq)$  through 2050.

This action also addresses certain aspects of the three petitions referred to above. First, this action responds to the one aspect of the three petitions that EPA found complete, namely petitioners' request that EPA change the listing of HFC-134a from acceptable to unacceptable in new MVAC systems. (See section V.B.) Second, regarding the remaining aspects of the three petitions, which EPA found to be incomplete, EPA has independently acquired sufficient information to address certain other requests made by the petitioners. EPA's action in this final rule may be considered responsive to certain aspects of those petitions such as: Changing the listing of certain HFCs used in specific aerosol uses from acceptable to unacceptable or acceptable, subject to use conditions; changing the listing of certain HFCs used in specific foams end-uses from acceptable to unacceptable for most uses; changing the listing of HFC-134a from acceptable to unacceptable for new stand-alone retail food refrigerators and freezers; and changing the listing of a number of refrigerant blends with higher GWPs from acceptable to unacceptable for new and retrofit stand-alone retail food refrigerators and freezers. Specifically, as explained in more detail in the sector-specific sections of this document, we are revising the listings for substitutes in the aerosols, foams, and refrigeration and air conditioning sectors that pose significantly greater overall risk to human health and the environment as compared with other available or potentially available substitutes in the specified end-uses.

Throughout the process of our discussions with the regulated community, we have sought to convey our continued understanding of the role that certainty plays in enabling the robust development and uptake of alternatives. Unfortunately, some of the key strengths of the SNAP program, such as its chemical and end-use specific consideration, its multi-criteria basis for action, and its petition process, tend to militate against some measures that could provide more certainty, such as setting specific numerical criteria for

environmental evaluations (e.g., all compounds with GWP greater than 150). That being said, we believe that the action we are taking today, and future action we may take, does provide additional certainty in the specific cases addressed. In addition, we remain committed to continuing to actively seek stakeholder views and to share our thinking at the earliest moment practicable on any future actions, as part of our commitment to provide greater certainty to producers and consumers in SNAP-regulated industrial sectors.

# V. What is EPA's final action concerning the HFCs addressed in this rule?

A. Aerosols

# 1. Background

The SNAP program provides listings for two aerosol end-uses: Propellants and solvents. Aerosols typically use a liquefied or compressed gas to propel active ingredients in liquid, paste, or powder form. In the case of duster sprays used to blow dust and contaminants off of surfaces, the propellant is also itself the active ingredient. Some aerosols also contain a solvent, which may be used in manufacturing, maintenance and repair to clean off oil, grease, and other soils.

Historically, a variety of propellants and solvents have been available to formulators. HCs (e.g., propane, isobutane) and compressed gases (e.g., CO<sub>2</sub>, N<sub>2</sub>, N<sub>2</sub>O, and compressed air) have long been used as propellants. Prior to 1978, the aerosol industry predominantly used CFCs. In 1978, in response to evidence regarding depletion of the earth's ozone layer, the United States banned CFC propellants, with few exceptions.

Many consumer products that previously used CFC propellants were reformulated or replaced with a variety of alternatives, including not-in-kind substitutes, such as pump sprays or solid and roll-on deodorants. Aerosol propellant substitutes included HCFCs, HCs, HFCs, compressed gases, and oxygenated organic compounds. However, since the 1990s HCFCs have been controlled substances under the Montreal Protocol and subject to regulation under the CAA, as amended in 1990, including a phaseout of production and import under section 605(b)-(c) and use restrictions under section 605(a).

2. What is EPA finalizing concerning aerosols?

For aerosol propellants, EPA proposed to list, as of January 1, 2016:

• HFC-125 as unacceptable;

international diplomacy a <sup>27</sup> See, *e.g.*, 60 FR at 31097.

- HFC–134a as acceptable, subject to use conditions, allowing its use only in specific types of technical and medical aerosols (e.g., MDIs) and
- HFC-227ea as acceptable, subject to use conditions, allowing its use only in MDIs.<sup>28</sup>

Today's action changes the status of HFC–125; HFC–227ea; blends of HFC–134a and HFC–227ea; and HFC–134a, as follows:

- We are changing the status of the aerosol propellant HFC–125 from acceptable to unacceptable as of January 1, 2016.
- We are changing the status of HFC–134a, HFC–227ea, and blends of HFC–134a and HFC–227ea from acceptable to unacceptable for use as aerosol propellants as of July 20, 2016 except for those uses specifically listed as acceptable, subject to use conditions.
- We are changing the status of the aerosol propellant HFC–227ea and for blends of HFC–227ea and HFC–134a from acceptable to acceptable, subject to use conditions, as of July 20, 2016, for use in MDIs approved by FDA.
- We are changing the status of the aerosol propellant HFC–134a from acceptable to acceptable, subject to use conditions, as of July 20, 2016, until January 1, 2018, for the following specific uses: Products for which new formulations require federal governmental review, including: EPA pesticide registration, military (U.S. Department of Defense (DoD)) or space agency (National Aeronautics and Space Administration (NASA)) specifications, or FDA approval (aside from MDIs); and products for smoke detector functionality testing.
- We are changing the status of the aerosol propellant HFC–134a from acceptable to acceptable, subject to use conditions as of July 20, 2016, for the following specific uses: Cleaning products for removal of grease, flux and other soils from electrical equipment or electronics; refrigerant flushes; products for sensitivity testing of smoke detectors; lubricants and freeze sprays for electrical equipment or electronics; sprays for aircraft maintenance; sprays

containing corrosion preventive compounds used in the maintenance of aircraft, electrical equipment or electronics, or military equipment; pesticides for use near electrical wires, in aircraft, in total release insecticide foggers, or in certified organic use pesticides for which EPA has specifically disallowed all other lower-GWP propellants; mold release agents and mold cleaners; lubricants and cleaners for spinnerettes for synthetic fabrics; duster sprays specifically for use on removal of dust from photographic negatives, semiconductor chips, specimens under electron microscopes, and energized electrical equipment; adhesives and sealants in large canisters; document preservation sprays; MDIs approved by FDA for medical purposes,<sup>29</sup> wound care sprays; topical coolant sprays for pain relief; and products for removing bandage adhesives from skin.

The change of status determinations for aerosols are summarized in the following table:

TABLE 2—CHANGE OF STATUS DECISIONS FOR AEROSOLS

End-use	Substitutes	Decision	Uses that are acceptable, subject to use conditions
Propellants	HFC-125	Unacceptable as of January 1, 2016.	None.
Propellants	HFC-134a	Unacceptable as of July 20, 2016 except for uses listed as acceptable, subject to use conditions.	From July 20, 2016 to January 1, 2018: Products for smoke detector functionality testing; products for which new formulations require governmental review, including: EPA pesticide registration, military or space agency specifications, or FDA approval (other than MDIs). As of July 20, 2016: Cleaning products for removal of grease, flux and other soils from electrical equipment; refrigerant flushes; products for sensitivity testing of smoke detectors; lubricants and freeze sprays for electrical equipment or electronics; sprays for aircraft maintenance; sprays containing corrosion preventive compounds used in the maintenance of aircraft, electrical equipment or electronics, or military equipment; pesticides for use near electrical wires, in aircraft, in total release insecticide foggers, or in certified organic use pesticides for which EPA has specifically disallowed all other lower-GWP propellants; mold release agents and mold cleaners; lubricants and cleaners for spinnerettes for synthetic fabrics; duster sprays specifically for removal of dust from photographic negatives, semiconductor chips, specimens under electron microscopes, and energized electrical equipment; adhesives and sealants in large canisters; document preservation sprays; FDA-approved MDIs for medical purposes; wound care sprays; topical coolant sprays for pain relief; and products for removing bandage adhesives
Propellants	HFC-227ea and blends of HFC- 227ea and HFC- 134a.	Unacceptable as of July 20, 2016 except for uses listed as acceptable, subject to use conditions.	from skin.  As of July 20, 2016: FDA-approved MDIs for medical purposes.

<sup>&</sup>lt;sup>28</sup> EPA did not explicitly state in our proposal whether blends of HFC–134a and HFC–227ea would also be acceptable subject to use conditions.

However, in general in the SNAP program, blends of acceptable aerosol propellants are also acceptable and do not require separate approval.

<sup>&</sup>lt;sup>29</sup> Includes veterinary purposes.

(a) What other alternatives are available?

EPA is changing the listing decisions for HFC-125, HFC-134a, HFC-227ea, and blends of HFC-134a and HFC-227ea, with some exceptions, because, as discussed in more detail in this section, for the uses for which we are listing these substitutes as unacceptable, alternatives (i.e., chemical compounds and technological options) are available or potentially available that reduce the overall risk to human health and the environment. Other substitutes listed as acceptable propellants include HFC-152a, HFO-1234ze(E), butane, propane, isobutane, CO<sub>2</sub> and other compressed gases, and dimethyl ether (DME). In addition, technological options include not-in-kind alternatives such as finger/ trigger pumps, powder formulations, sticks, rollers, brushes, and wipes. These alternatives have GWPs ranging from zero to 124 compared with HFC-134a's GWP of 1,430, HFC-227ea's GWP of 3,220 and HFC-125's GWP of 3,500.30 All of these alternatives, both the ones remaining acceptable and those for which we are changing the listing, have an ODP of zero, are relatively low in toxicity, and are capable of remaining below their respective exposure limits when used as aerosol propellants. In addition to GWP, some of the other environmental and health attributes that the SNAP program considers that differ for these alternatives include impacts on local air quality and flammability. For example, butane, propane, isobutane, and DME are VOC as well as being flammable. Butane, propane, isobutane, and DME are not excluded from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of state implementation plans (SIPs) to attain and maintain the national ambient air quality standards. Thus, these propellants are subject to federal, state, and local regulation that may prevent their use as a propellant in aerosols in some states and counties that have nonattainment areas for ground-level ozone and restrict their use under this action. HFC-125, HFC-134a, HFC-227ea, HFC-152a, HFO-1234ze(E), and the compressed gas CO2 are exempted from the definition of VOC under these regulations and their use is expected to have negligible impact on ground-level ozone levels. As well as HFC-152a, HFO-1234ze(E), and CO<sub>2</sub>, compressed

 $N_2$  and not-in-kind alternatives are not VOC.

The aerosols industry is generally familiar with how to address flammability risks. The aerosols industry has been using flammable compounds, including flammable propellants, for decades, consistent with OSHA requirements addressing flammability. There may be greater flammability risks for some specific uses of aerosol products because of their use in situations where there is a source of heat or electrical energy that could cause a fire (e.g., use on energized electrical equipment). Concerns with flammability occur more with industrial products, often referred to as "technical aerosols." For further discussion on consumer aerosols, technical aerosols. and medical aerosols, see the NPRM at 79 FR 46136 through 46138 (August 6, 2014).

There are a number of alternatives with GWPs lower than the GWPs for the substitutes that we are listing as unacceptable and that are not defined as VOC for purposes of SIPs, including: HFC-152a with a GWP of 124, HFO-1234ze(E) with a GWP of 6, and CO<sub>2</sub> with a GWP of 1. CO2 and HFO-1234ze(E) are nonflammable under ambient temperature conditions, while HFC-152a is flammable, but less so than hydrocarbons or DME. All three have GWPs significantly lower than those of the HFCs for which we are changing the listing (range of GWPs from 1,430 to 3,500 for HFC-134a, HFC-227ea and HFC-125).

(1) Aerosols With Flammability and Vapor Pressure Constraints

Aerosols for industrial and commercial uses often require nonflammability and in some cases, specific vapor pressure criteria. For example, nonflammable aerosols are needed for use on energized electrical circuits, where sparking can create a fire or explosion hazard. Of the different alternatives that have previously been listed as acceptable, the nonflammable options at room temperature include HFC-125, HFC-134a, HFC-227ea, HFO-1234ze(E), compressed gases including CO<sub>2</sub> and N<sub>2</sub>, and not-in-kind products. At slightly higher temperatures (30 °C or 85 °F), HFO-1234ze(E) exhibits lower and higher flammability limits, and thus in theory could catch fire under specific conditions of concentration and applied energy. Some aerosol product formulators have expressed concern that the lower vapor pressure of HFO-1234ze(E) and the significantly higher vapor pressure of CO2 and other compressed gases may not provide

adequate performance in propelling the contents of a can for technical aerosols or may exceed Department of Transportation pressure requirements under elevated temperatures (ITW Polymers Sealants, 2014). For comparison, the vapor pressures of HFO–1234ze(E), HFC–134a, and CO<sub>2</sub> at 20 °C are 422 kPa, 655 kPa, and 5,776 kPa, respectively.

Based on the information available today, EPA believes it cannot list HFC–134a as unacceptable for all aerosol uses. Thus, we are creating a use condition that would restrict use of HFC–134a to specific uses for which alternatives are not currently or

potentially available.

Both HFC-227ea and HFC-125 have significantly higher GWPs than HFC-134a (HFC–227ea's GWP is 3220 and HFC-125's GWP is 3500) or other substitutes that could be potentially used where flammability is a concern, and there is not a significantly different level of risk based on the other factors that we consider. Thus, EPA has determined that HFC-227ea and HFC-125 pose significantly more risk than other available substitutes and EPA is changing their listing from acceptable to unacceptable in most uses where HFC-134a may be used to mitigate flammability risks. We note that we are not aware of any use of HFC-227ea or of HFC-125 in industrial aerosols to mitigate flammability risks.

# (2) Aerosols for Specific Medical Uses

For medical aerosols, there are special needs to address safety and toxicity. Furthermore, in order for a substitute to be available for use in medical devices, the device using the substitute must first be reviewed and approved by the FDA.

FDA has approved medications for use in MDIs using HFC-134a, HFC-227ea, and blends of these two HFCs as propellants. No medications have been approved for use in MDIs using other propellants. Although some dry powder inhalers that are not-in-kind substitutes are approved by FDA, these alternatives do not work for some situations. Thus, we cannot conclude that there are other alternatives available for use in MDIs that pose lower risk than HFC-134a, HFC-227ea, or blends of these two. In addition, it is our understanding that because of differences in the solubility of water in HFC-134a and HFC-227ea, there are some medications that are sensitive to the presence of water for which only HFC-227ea may be used in an MDI.

For other medical uses, EPA is aware of medical aerosols that currently are using hydrocarbons or DME as the propellant, as well as not-in-kind

<sup>&</sup>lt;sup>30</sup> GWP values cited in this final rule are from the IPCC Fourth Assessment Report (AR4) unless stated otherwise. Where no GWP is listed in AR4, GWP values shall be determined consistent with the calculations and analysis presented in AR4 and referenced materials.

alternatives for uses such as antifungals, calamine sprays, freeze sprays for wart removal, and liquid bandages (ICF, 2014a). However, EPA does not have information that alternatives other than HFC–134a are available and are approved by FDA as propellants in wound care sprays; topical coolant sprays for pain relief; and products for removing bandage adhesives from skin.

The available substitutes for medical devices are limited to those approved by FDA, and the available substitutes differ by the type of product and medical conditions treated. For these reasons, we are listing HFC–134a, HFC–227ea and blends of HFC-134a and HFC-227ea as acceptable, subject to use conditions, for specific uses for which other alternatives that pose lower overall risk to human health and the environment are not currently or potentially available. The use conditions limit use of HFC-227ea and blends of HFC-227ea and HFC-134a to MDIs approved by FDA and limit use of HFC-134a to MDIs approved by FDA and the other medical uses listed above.

HFC-125 has a GWP of 3,500, which is higher than the GWP of all other alternatives that are available for use as aerosol propellants (HFC-227ea has a GWP of 3,220; HFC-134a has a GWP of 1,430; HFO-1234ze(E) has a GWP of 6). Like HFC-134a, HFC-227ea, CO2 and HFO-1234ze(E), it is VOC-exempt, nonflammable and low in toxicity. We are not aware of any medical or other aerosols currently using HFC-125, or of any FDA approval for aerosols using HFC–125. For these reasons, we have determined that there are other available substitutes that pose lower overall risks to human health and the environment in this use and we are changing the listing of HFC-125 from acceptable to unacceptable.

For more information on the environmental and health properties of the different aerosol substitutes, please see the proposed rule at 79 FR 46137–46138 and a technical support document that provides the additional **Federal Register** citations (EPA, 2015d) in the docket.

#### (b) When will the listings change?

On or after January 1, 2016, aerosol products may not be manufactured with HFC–125 and on or after July 20, 2016, aerosol products may not be manufactured with HFC–134a or HFC–227ea, or blends thereof except for the specific uses allowed under the use conditions. In addition, as of January 1, 2018, HFC–134a will be unacceptable for certain uses, and aerosol products for those uses may not be manufactured with HFC–134a as of that date:

- Products for which new formulations require U.S. federal government review, including: EPA pesticide registration, military or space agency specifications, and FDA approval (aside from MDIs); and
- products for functional testing of smoke detectors.

In the case of HFC-125, EPA is unaware of any products using HFC-125, and no public commenters mentioned the existence of such products or requested a date other than the proposed date of January 1, 2016.

We are setting July 20, 2016, as the date on which the status of HFC-134a, HFC-227ea, and blends thereof will change to unacceptable, or to acceptable, subject to use conditions, for certain specific uses. For those uses that would no longer be allowed as of July 20, 2016, this timeframe will allow formulators and packagers of aerosols to make the necessary changes. (ICF, 2014a; Honeywell, 2014a). A number of formulators have already been testing, and in many cases introducing, new formulations with alternatives that remain listed acceptable. This timing will provide affected aerosol manufacturers and packagers sufficient time to change and test formulations and, to the extent necessary, to change the equipment in their factories.

For two aerosol uses, continued use of HFC-134a will be allowed under the use conditions until January 1, 2018. EPA is providing this longer transition time for these two uses because of additional safety precautions and approvals outside of the control of the aerosol formulator that must be addressed before transitioning. The first category is those that must undergo specific federal governmental reviews: EPA pesticide registration under the Federal Insecticide, Fungicide, and Rodenticide Act, military or space agency specifications, and FDA approval. The second category is aerosol products for functional testing of smoke detectors, which have National Fire Protection Association (NFPA) 72 requirements adopted in building codes. These types of aerosols must be tested not only for performance but also reviewed by third parties for compliance with regulatory or code requirements or military specifications. Given both the safety implications of insufficient testing and the additional time required for third-party testing and/or governmental approval that is not required for other aerosol formulations, we have determined that alternatives that reduce overall risk will not be available for these uses until January 1, 2018.

As of the change of status dates, products cannot be manufactured with HFC-134a or HFC-227ea or blends thereof except for the aerosol product types that are listed under the use conditions. Products manufactured prior to the change of status date may still be sold, imported, exported, and used by the end-user after that date. As discussed below in the responses to comment, restricting use of aerosols by the end-user, as well as restricting the sale of previously manufactured aerosols, may disrupt the market and may not result in environmental benefits.

3. How is EPA responding to comments about this end-use?

#### (a) Timeline

Comment: EPA received comments from a number of commenters on the status change date of HFC-134a, HFC-227ea, and HFC-125 as an aerosol propellant. Members of the aerosol industry proposed alternate years ranging from 2018 to 2021, always in reference to HFC-134a or to "technical" aerosols. Reasons provided for these dates included aligning with the European Union's (EU) timeline of January 1, 2018; a need for at least one to two more years to complete reformulation and all testing required; and additional time of two to five years to complete approval processes: e.g., Underwriters Laboratories (UL) approvals to meet NFPA requirements, EPA pesticide registration or testing for conformance with military specifications. Members of the aerosol industry also suggested that January 1, 2016, is too soon to transition away from HFC-134a because of the need for coordination with other regulatory requirements, because of business considerations including the timing of the need for budgeting for capital expenditures, developing and implementing worker education, negotiating contracts between aerosol formulators and retailers, and for technical reasons such as stability issues with HFO-1234ze(E), one of the alternatives that remains acceptable for use. NRDC and IGSD stated that EPA must maintain its 2016 timeline for transition to ensure that important climate reductions are realized.

Response: In determining when alternatives that reduce overall risk will be available for use, EPA considers technical constraints on the use of other alternatives, including when other alternatives may be used consistent with safety requirements. Unlike some enduses, such as some of the refrigeration end-uses, there are a much wider variety

of uses with a much broader range of considerations under the aerosol propellant end-use. While there are exceptions, as we address in this action, for most of these wide-ranging uses, we do not anticipate significant hurdles to transitioning to alternatives. Based on information provided by the manufacturer of HFO-1234ze(E), a number of their customers have been able to develop and introduce aerosol products using HFO-1234ze(E) in a matter of months rather than years. Except in limited cases, as discussed below, commenters requesting a longer transition period did not provide concrete support for why more time for specific uses is needed, resting only on general statements that time is needed for "formulation" and "testing." Based on the information available showing that manufacturers have been able to transition relatively quickly, but also recognizing that there may be some variation in the time needed for specific uses, we are establishing a change of status date of July 20, 2016—roughly seven months later than the proposed date of January 1, 2016. This will allow approximately one year from the time this rule is issued in which manufacturers should be able to address their generalized testing and reformulation concerns. Also, HFC-134a remains acceptable, subject to use conditions, for many uses, reducing the number of products for which companies must reformulate, test, and transition to other alternatives.

For certain aerosol products using HFC-134a that must go through a federal government or other third-party approval process for new formulations, we are establishing a change of status date of January 1, 2018. These products include those needing EPA pesticide registration, testing to U.S. military or space agency specifications, and FDA approval (aside from MDIs). In addition, we are establishing a change of status date of January 1, 2018, for a product that requires extensive testing to NFPA standards, specifically for smoke detector functional testing. Based on information received during the public comment period, we have determined that for these specific uses, alternatives that pose less risk are not available until these testing and registration processes are complete.

EPA disagrees that we should align the timelines in this rule with the EU timelines. The EU regulations rely upon different authority than the SNAP program, and reflect the European context. We believe it is appropriate for EPA decisions to base timelines upon when alternatives that reduce overall risk are available in the United States.

Comment: National Aerosol Association (NAA), Radiator Specialty Company (RSC), LPS Laboratories, **Consumer Specialty Products** Association (CSPA), and Aeropres commented that there is currently no industry consensus on the safe handling of HFO-1234ze(E) (and "any alternative products") in aerosol plants. CSPA states that the CSPA Aerosol Propellants Safety Manual will need to be updated to include new propellants like HFO-1234ze(E), and that the consensus guidelines will then be used to assure that fire and building codes are updated to properly cover new propellants. The commenter also states that while they seek consensus on updating their safety manual, companies are able to proceed using the guidance provided by the supplier, but many CSPA members prefer to await industry consensus standards. LPS Laboratories comments that applicable codes need to be updated before other alternatives can be used and suggests that a January 1, 2018, date for listing HFC-134a as unacceptable is more appropriate.

Response: In the absence of industry consensus guidance, a number of aerosol formulators are already manufacturing products safely using HFO-1234ze(E) relying upon safety guidelines developed by the chemical producer. No commenters raised, and we are unaware of, any specific safety concerns that are not addressed in this guidance issued by the chemical producer. CSPA mentioned updating fire and building codes using the consensus guidelines, but did not state how these are related and also indicated that some companies have been able to move ahead without updates to fire and building codes based upon the guidance. For that reason, we do not believe there is a basis for determining that HFO-1234ze(E) is not available for safe use until January 1, 2018, as suggested by commenters.

#### (b) Sell-Through Period

Comment: Honeywell stated that there should be a limited sell-through period to prevent stranded inventories for aerosol products, while avoiding delays in the transition to low-GWP substitutes. The commenter suggested that EPA prohibit the sale, import and export of aerosol products manufactured with unacceptable substitutes by no later than January 1, 2017. The commenter also suggested that the sell-through period should apply only to products that were manufactured prior to January 1, 2016, and that have entered the distribution channel.

Response: EPA disagrees with the commenter's suggestion that a limited

sell-through period would be sufficient. Based on past experience with implementing a limited sell-through period for certain kinds of aerosols containing CFCs and with implementing an unlimited sell-through period for other aerosols, we found that a limited sell-through can result in market disruption and can strand inventory. Further, a limited sell-through period does not necessarily preclude emissions of HFCs to the environment because while manufacturers and distributors would need to dispose of stranded inventory, there is no current requirement prohibiting venting of the contents to the atmosphere (unlike for refrigeration or MVAC). In this rule, we allow new cars or new stand-alone refrigeration equipment manufactured with HFC-134a before the change of status date to be used and serviced after the change of status date to avoid market disruption, creation of stranded inventory, and perverse incentives for releasing refrigerant to the environment; a closely analogous treatment for aerosols is to allow manufacturers and distributors to sell and end users to use aerosol products manufactured before the relevant change of status date. Finally, because of the relatively short period from issuance of EPA's final rule to the compliance date, we do not expect that there will be a large accumulation of inventory. Accordingly, this rule allows for an unlimited sellthrough and use period for covered aerosol products manufactured before the change of status date.

#### (c) Use Conditions

Comment: Honeywell, the producer of HFO-1234ze(E), stated that there are either commercially available products or shelf-ready products that have not yet been commercialized that do not contain HFC-134a for some of the uses for which EPA proposed to change the status of HFC-134a, to acceptable, subject to use conditions, including cleaning products for electronics, sprays for aircraft maintenance, and dusters.

Response: EPA agrees, and we note that the uses identified in the use conditions encompass a variety of highly specific uses. While products without one of these substitutes or a blend of these substitutes might be used in one specific use, this does not hold true for the entire range of uses in the use category. In particular, this is the case for uses where flammability is of concern, such as for electronics cleaning and specialty dusters that are used on high-voltage equipment. In the future, additional testing may indicate that other alternatives, such as HFO-1234ze(E), can be used safely even

under conditions where flammability is of concern, but the information available to date is not currently sufficient. Thus, we agree with other commenters from the aerosol industry, such as CSPA, that HFC–134a continues to be necessary in specific uses where other alternatives that pose less overall risk to human health and the environment are not available.

Comment: Arkema asked whether EPA is proposing that HFC–227ea continue to be acceptable for MDIs because of "the volumes or a record of unique suitability for a particular purpose," when HFC–134a might pose lower overall risk compared to HFC–227ea, since its GWP is less than half that of HFC–227ea.

Response: Arkema's comment seems to suggest that we should list HFC-227ea as unacceptable for use in MDIs, because it has a higher GWP than HFC-134a; we disagree. Although the GWP for HFC-227ea is significantly higher than that for HFC-134a, our understanding is that there are technical reasons why HFC-134a may not perform adequately as a propellant in MDIs using certain kinds of medications. For example, because some medications could react or degrade in the presence of moisture, and water is much more soluble in HFC-134a than in HFC-227ea, further technical work is needed to determine if HFC–134a is able to serve as a propellant in all MDIs. Currently, it is our understanding that for those types of medications, there are no alternatives to HFC-227ea that pose lower overall risk to human health and the environment.

Comment: The International Pharmaceutical Aerosol Consortium (IPAC) and Mexichem Fluor, Inc. (Mexichem) suggested using the same language for the listing for MDIs for HFC-227ea as for HFC-134a. IPAC, Mexichem, and King & Spaulding suggested revising the language to apply to a wider group of medical uses, including the treatment of conditions or diseases of other organs (for example diabetes) where aerosols can be used for systemic delivery through the lung or nose, or that HFC-134a and HFC-227ea should be allowed for any medical MDI that has been FDA-approved regardless of disease condition treated. One of the commenters also stated it should be made clear that blends of HFC-134a and HFC-227ea are also acceptable for such

Response: EPA agrees with the commenters that the lists of medical conditions treated with MDIs should be consistent for HFC-134a and HFC-227ea. Additionally, we agree that the

language should more clearly specify our intent, which is to cover all MDI uses for which FDA has approved HFC-134a, HFC-227ea, or blends of these HFCs. This would include the wider group of medical uses suggested by King & Spaulding, including the treatment of conditions or diseases of other organs (for example diabetes) where aerosols can be used for systemic delivery through the lung or nose. It is our understanding that HFC-134a and HFC-227ea are the only available alternatives for MDIs approved by FDA, with dry powder inhalers as an additional possible not-in-kind alternative in limited cases. Thus, we believe that there are no other alternatives available or potentially available for all MDIs approved by FDA that pose less risk overall to human health and the environment. We have revised the wording of the regulatory listing decision to make clear that the use condition for HFC-134a, HFC-227ea, and blends of HFC-134a and HFC-227ea applies to all MDIs approved by FDA.

Comment: HSI (Fire & Safety Group, LLC), Honeywell, DuPont, and EIA commented that there are available alternatives and there is sufficient supply of these alternatives to support EPA's proposed change of status decisions for the aerosol propellants end-use.

Response: EPA agrees with the commenters that, for the most part, there is a sufficient supply of alternatives that will support a transition away from the substitutes that we have concluded provide a greater risk to human health and the environment. However, as discussed in more detail above and in response to other comments, in some specific cases we received information that demonstrates the existence of technological challenges that support a later date for the change in status. In those cases, we are providing a later date

Comment: Commenters in the aerosol industry commented on situations where some alternatives other than HFC-134a are not effective or feasible. NAA commented that if CO2 were feasible, it would already be used. LPS Laboratories commented that formulators must consider chemical compatibility with formulations; for example, CO<sub>2</sub> cannot be used with water-based formulations due to the formation of carbonic acid. LPS Laboratories commented that nitrogen has very limited uses due to its lack of solubility and the substantial pressure drop that occurs as the product is used.

Response: EPA recognizes that not all alternative propellants work in every particular formulation. The commenters have described specific situations where CO<sub>2</sub> and nitrogen may not be appropriate propellants. However, other alternatives are also listed as acceptable. HFO–1234ze(E) and HFC–152a have some physical similarities with HFC–134a and the commenters do not claim that these other alternatives are not available.

Comment: NRDC and IGSD urged the Agency to deny any requests in the aerosols sector for additional exemptions.

Response: EPA has considered the comments and information submitted during the comment period and is adding a limited number of uses to the use conditions that would allow continued use of HFC–134a, HFC–227ea, or blends thereof for the reasons provided elsewhere in this preamble.

Comment: Honeywell, NAA, and CSPA commented on the nonflammability of HFO-1234ze(E). NAA indicated that HFO-1234ze(E) was found to be nonflammable by a number of standard tests (e.g., ASTM E-681) and aerosol flammability test methods (e.g., flame extension, enclosed space ignition), as well as by a non-standard test including a test that found no ignition up to temperatures greater than 900 °F. Honeywell commented that while it is accurate to say that HFO-1234ze(E) may exhibit vapor flame limits at elevated temperatures, that is only one of many properties that must be taken into consideration when characterizing HFO-1234ze(E) and its usefulness in formulating nonflammable aerosol products. This commenter also provided additional information about other tests on the flammability of HFO-1234ze(E). CSPA said that there is still some concern about the potential for flammability at higher ambient temperatures, and that CSPA member product marketers, formulators and manufacturers are working to assure that specific products in various categories can be formulated, manufactured and used safely and effectively.

Response: Based on the information available to EPA at this time, we agree that HFO–1234ze(E) is nonflammable in most situations that aerosols will be used. However, we have not seen results of testing that cover all of the types of products for which there are concerns about the need for a nonflammable aerosol propellant, such as aerosol products used on energized circuits or other electrical equipment. For other uses, where we have evidence of product-specific testing on HFO–

1234ze(E) showing nonflammability (e.g., tire inflators), we have concluded that the flammability risks of HFO–1234ze(E) are not a significant concern.

Comment: Several commenters discussed flammability concerns for tire inflators, with some suggesting that they should be added as a use for which HFC-134a is acceptable, subject to use conditions, others suggesting a later change of status date, and others supporting the proposal. NAA and RSC stated that due to past accidents traced to flammability of tire inflators, it is necessary to test all aspects of the inflators to ensure that there are no flammability issues with HFO-1234ze(E). RSC and Honeywell commented on the specific testing required to ensure that new tire inflators using HFO-1234ze(E) are nonflammable, because of the possibility of ignition sources such as application of a torch to the rim of the tire or sparking from metal tools contacting a steel belt during tire repair. ITW Global Tire Repair commented that previous Aerosol Tire Inflators were flammable and there were several accidents in which tire repair professionals were injured when a spark ignited the product. This commenter also stated that EPA should not dismiss the need for a nonflammable product because other aspects of motor vehicles are flammable; tires and wheels have not been designed and engineered to contain flammable products, unlike many other flammable products in motor vehicles. CSPA referred to a March, 1999 recall from the National Highway Traffic Safety Administration (NHTSA) recall for 32 million units of an aerosol tire inflator due to injuries caused by the product's flammability. Mexichem comments HFO–1234ze(E) requires further evaluation before implementation for emergency tire inflators and sealers because of its flammability and uncertainty regarding its compatibility with sealants. Honeywell, the manufacturer of HFO-1234ze(E), commented that third-party testing of aerosol tire inflators using HFO–1234ze(E) found them to be nonflammable.

Response: We acknowledge that there have been reports of accidents associated with use of flammable tire inflators in the past, particularly affecting tire repair professionals. Not all manufacturers of tire inflators agree that a nonflammable propellant is necessary, given there are tire inflators using hydrocarbons already on the market. Although HFO–1234ze(E) can ignite under higher temperature conditions using the standard test ASTM E 681, a relevant question is

whether data indicate that an aerosol tire inflator using HFO-1234ze(E) would be flammable under the pressure, temperature, and likely ignition sources specific to this use. This will ensure a relevant risk comparison and will not compare to other flammable substances used in other parts of a motor vehicle. One manufacturer of aerosol tire inflators has tested a formulation using HFO-1234ze(E) and has found it is nonflammable under the conditions that exist for use of a tire inflator (RSC, 2014). Therefore, other alternatives are available besides HFC-134a that sufficiently mitigate flammability risks for this use. Concerning RSC's suggestion for a change of status date of January 1, 2018, to give sufficient time for additional testing, the commenter provided insufficient information on the types of testing or timeframes involved to warrant providing additional time. Further, in this final rule, we are providing roughly an additional seven months beyond the date in the proposal to meet commenters' general comments about requiring additional time for testing. Based on the information available, HFO-1234ze(E) is an option that other manufacturers of aerosol tire inflators are using to formulate products that are not flammable under the conditions expected for that use.

Comment: Commenters from the aerosol industry requested that EPA include additional uses for which HFC-134a is acceptable, subject to use conditions. These uses include certain aerosols used for testing smoke detector sensitivity and "emergency safety horns exclusively used for marine emergency situations and/or industrial emergencies and evacuations." Reasons cited include allowing time for developing and approving new smoke detector sensitivity testing equipment and the need for nonflammability because emergency safety horns function where flames or other ignition sources are present. An environmental group states that it disagrees with comments that request continued use of HFC-134a in freeze sprays, tissue freezes, portable safety horns and personal defense sprays, as these applications can use other lower-GWP alternatives such as dimethyl ether, HFO-1234ze(E), and

Response: For aerosols used for smoke detector sensitivity testing, EPA received information from a manufacturer of such products that this use requires redesign of equipment for testing smoke detectors, and not just reformulation of the aerosol. This information indicates that the equipment for such testing is designed based on the vapor pressure of HFC—

134a and would not work with another propellant. Therefore, we are adding aerosols for sensitivity testing of smoke detectors to the list of use conditions.

For portable safety horns, personal defense sprays, and freeze sprays for wastes (as opposed to electronic freeze sprays), there are other alternatives that are available or potentially available that reduce overall risk to human health and the environment. Products using HFO–1234ze(E) already exist or are in development for these uses. EPA received no information indicating that alternatives other than HFC–125, HFC–134a or HFC–227ea, or blends thereof, cannot be safely used in tissue freeze sprays.

Comment: ITW Polymers Sealants requested that EPA either clarify that canister adhesives and sealants are not considered to be aerosols, or else that EPA add this use to the list of use conditions for HFC-134a. ITW Polymers Sealants provided information indicating that flammability of the propellant is of concern in the fabrication facilities with this use, and that use of hydrocarbon propellants would exceed VOC limits set for these products in many areas of the country. The commenter also indicated that HFO-1234ze(E),  $CO_2$ , and  $N_2$ , the only other propellants that would address flammability concerns for this use besides HFC-134a, have vapor pressures outside of the range that would provide sufficient performance. In the absence of sufficient vapor pressure, as with HFO-1234ze(E), the commenter claims that there will be performance problems such as lower bond strength or bumps and mounds in furniture surfaces; with the higher pressure propellants N2 and CO<sub>2</sub>, the commenter states that these will result in exceeding Department of Transportation internal pressure limits at elevated temperatures.

Response: We do consider canister adhesives and sealants to be aerosols because they are pressurized containers and they use a propellant, as opposed to solely mechanical means, to expel the other ingredients of the formulation from the container. The information provided by the commenter on vapor pressure concerns is plausible, based on the relative vapor pressures of the different propellants. It is possible for fabrication facilities to use flammable adhesives and propellants safely, but it would require time to make the necessary upgrades to address these risks. It is also of concern that in VOC nonattainment areas, large amounts of hydrocarbons in these large canister adhesive containers would cause canister adhesives and sealants to exceed their VOC limits. Of the

available propellant options that are not VOC or are exempted from the definition of VOC—HFC-134a, HFO-1234ze(E), CO<sub>2</sub>, and N<sub>2</sub>—to date, only HFC-134a has been shown to be in a pressure range that provides sufficient performance. Thus, it is likely that HFC-134a is the only available propellant for canister adhesives and sealants in many areas of the country. Therefore, this final rule adds adhesives and sealants in large canisters to the list of uses where HFC-134a is acceptable, subject to use conditions.

Comment: A number of members of the aerosol industry requested that EPA consider adding aerosols for use on energized electrical equipment as a use for which HFC–134a is acceptable, subject to use conditions. Specific products mentioned include dusters for use on live electric circuits, contact cleaners for energized circuits, mold cleaners, and electronic freeze sprays.

Response: EPA agrees that, given the high temperatures and high electrical energy present on energized electrical equipment, it is necessary to retain the option of a propellant that remains nonflammable at high temperatures. As described elsewhere in the preamble, compressed gases such as CO<sub>2</sub> and N<sub>2</sub> may be nonflammable but are not appropriate in some situations, due to pressure drop-off and reactions with other formulation ingredients. HFO-1234ze(E) is nonflammable in many situations, but it is not yet clear if it remains nonflammable in the presence of the high temperatures and high electrical energy in the specific uses mentioned by the commenters. If additional information becomes available showing that HFO-1234ze(E) remains nonflammable in such situations, we may revisit this decision in the future. In this final rule, we are adding mold cleaners, electronic freeze sprays, and dusters for use on energized electrical circuits to the list of aerosol products that may continue to use HFC-134a under the use conditions. We consider electrical contact cleaners for energized electrical equipment to be part of the use "cleaning products for removal of grease, flux and other soils from electrical equipment or electronics" and therefore covered by the use condition.

Comment: MicroCare, a company specializing in cleaning, and Traulsen, a manufacturer of commercial refrigeration equipment, request that refrigeration system flushes be added to the use condition specifying which enduses may still use HFC–134a. They explain that after removing refrigerant and flushing any oils or particulates left, the lines are brazed, soldered or welded

back together at high temperatures well above the level at which HFO–1234ze(E) becomes flammable (e.g., above 1,995

CSPA stated that it should be clarified that "Cleaning products for removal of grease, flux, and other soils from electrical equipment or electronics' includes cleaners for refrigeration coils because of similar requirements for nonflammability. NAA stated that its members did not reach consensus on whether refrigerant flushes should be added to the acceptable list. This commenter states that it is common practice in the industry to remove flushing agents from lines and blowing them dry with nitrogen or compressed air after flushing, which eliminates risks posed by welding lines after flushing.

Response: Because of the extremely high temperatures cited by MicroCare and Traulsen that may be present in a refrigerant line after flushing, EPA agrees that it is necessary to have a nonflammable propellant available for refrigerant flushes. The term "refrigerant flushes" also refers to cleaners for refrigerant coils. Although nitrogen can be used to purge refrigerant lines to remove refrigerant flushes prior to brazing or welding, it is not clear that this is a universal practice in the industry. Therefore, we are adding refrigerant flushes to the use condition specifying uses that may continue to use HFC-134a.

Comment: SAE International and Alliance of Automobile Manufacturers (AAM) commented that there are aerosol products available for servicing MVAC systems which contain additives in a can propelled by HFC-134a which the commenters believe should be acceptable, subject to use conditions. The commenters stated that the use of propellants other than HFC-134a could cause technical problems, could contaminate refrigerant so that EPAapproved Recovery, Recycling and Recharging (RRR) equipment cannot be used, or could be incompatible with SAE standards if the propellant goes into the MVAC systems.

Response: EPA considers an aerosol can containing HFC–134a used to recharge an MVAC system to fall under the MVAC end-use and not the aerosol propellant end-use. Under the SNAP lists for the MVAC end-use, HFC–134a remains an acceptable substitute for servicing existing systems. An aerosol can containing HFC–134a refrigerant and oil or leak sealant, which is used to inject oil or repair leaks and to then recharge MVAC systems, would also fit in the MVAC end-use and remains acceptable for use on existing systems. These cans must have the unique

fittings required by SNAP for HFC-134a as a motor vehicle air conditioner refrigerant. However, an aerosol can primarily intended to inject additives, e.g., dye, rather than to add HFC-134a as a refrigerant would be considered an aerosol, and use of HFC-134a as the propellant would not be allowed as of July 20, 2016, under this final rule. We do not consider this type of product to fit under the commenter's request for products for servicing. Further, we disagree with the commenter that it is necessary to have a propellant that is the same as the refrigerant used in MVAC. We note that in the future, HFO-1234yf or other refrigerant substitutes will be used as a refrigerant in many vehicles; thus, in the future, automotive products will need to be formulated to include propellants other than HFC-134a, as well as formulated with propellants that are different from the refrigerant used in the MVAC system.

Comment: DuPont recommended that EPA establish use conditions rather than narrowed use limits in implementing any changes of status for HFCs used in aerosols. The commenter stated that acceptable conditions of use are a relatively straightforward, selfimplementing regulatory approach that would limit the burden on aerosol companies, most of which are small businesses, in complying with the changed status. DuPont commented that narrowed use limits are a much more administratively intensive approach for both the Agency and the regulated community, and would impose significant burdens on these small businesses, as well as on EPA.

Response: We agree with the commenter that narrowed use limits are more administratively burdensome. We are establishing use conditions in the final rule.

(d) HFC Consumption and Climate Impact of Aerosols

Comment: DuPont, Mexichem and the **Consumer Specialty Products** Association (CSPA) commented on the relatively small contribution of nonmedical aerosols to HFC consumption, stating that it represents between 1 and 2% of all HFC consumption. A producer of tire inflators noted that tire inflators make up less than 0.2% of the current use of HFC-134a. Mexichem stated that the continued availability of HFC-134a for the small businesses and consumers that produce/rely on aerosol products, will make no appreciable difference to EPA's goal of reducing GHG emissions, because aerosol products account for only five percent of total HFC consumption, and of that portion, only

24% serve non-medical purposes. This commenter suggested that EPA should accommodate these uses through exemptions or a delay in the "delisting" of HFC–134a. In contrast, Honeywell mentions that its new technologies in the aerosol sector could reduce GHG emissions by more than 6 MMTCO<sub>2</sub>eq per year in 2016.

Response: EPA agrees that the aerosol sector comprises a small portion of the total consumption of HFCs. However, we disagree that we should not change the status of HFCs for the aerosol propellant end-use because GHG emissions from that end-use are small. We note that any given end-use within the 50-some SNAP end-uses may be relatively small compared to the whole. Section 612(c) of the CAA directs EPA to publish lists of substitutes prohibited for specific uses and safe alternatives for specific uses. Thus, we make our decision by considering the overall risk to human health and the environment posed by the available or potentially available substitutes within each enduse, rather than comparing risks in different end-uses to each other. We disagree with the commenter's suggestion that EPA provide a later change of status date for aerosol uses because of their relatively low GHG emissions. Instead, EPA considers the time in which alternatives are available for use, which involves the feasibility of implementing alternatives with lower overall impacts on human health and the environment. EPA appreciates the information provided by one commenter that indicates that for the aerosol sector, the change in status for HFC-134a, HFC-227ea, and HFC-125 could reduce GHG emissions by more than 6 MMTCO<sub>2</sub>eq per year.

#### (e) Small Business Impacts

Comment: Falcon Safety Products comments that they transitioned from HCFCs to HFCs in 1993, after which it began transitioning from HFC-134a (with a GWP of 1,430) to HFC-152a (with a GWP of 124) in compressed gas dusters, at a significant cost to its company, in terms of retooling and installing new gas tanks and filing lines. Falcon Safety Products supports the EPA's high-GWP emissions reduction efforts, but believes that they should not negatively impact small businesses or have a detrimental impact on the safety, affordability, or efficacy of its product categories. Falcon Safety Products comments that transitioning to HFO-1234ze(E) is very expensive for small businesses like itself, in terms of changing tanks, filling lines, and revising labels and marketing materials.

Response: EPA did not propose and is not finalizing a change in status for HFC–152a in aerosols. See preamble section V.A.3 for EPA's status changes for HFCs in the aerosols sector, and supporting document Economic Impact Screening Analysis for Regulatory Options to Change Listing Status of High-GWP Alternatives (ICF, 2014f; ICF, 2015b).

#### (f) Imports

Comment: CSPA expressed concern about noncomplying products from offshore, which they state has been a large problem in the past. CSPA stated that for retail products, more time is needed to adjust contracts and to work with EPA to ensure that CSPA member complying products are not displaced by non-complying products from offshore.

Response: For aerosol products, the rule applies to imported products as well as to manufacture of products in the United States. By providing a full year after finalization of the rule before a change of status is required for the HFCs covered by this action known to be in current use for aerosol product manufacture, there is now additional time to adjust contracts and work with retailers. EPA welcomes the suggestion that we should work together with the aerosol industry and retailers to avoid sale of non-complying products that might be imported.

# B. MVAC Systems for Newly Manufactured Light-Duty Motor Vehicles

## 1. Background

MVAC systems cool passenger cars, light-duty trucks, buses, and rail vehicles. CFC-12 was the refrigerant historically used in the manufacture of MVAC systems. HFC-134a, along with a number of other substitutes, was found acceptable for use in light-duty vehicles in 1994 and at the same time, CFC-12 was being phased out of production. By the mid-1990s, use of CFC-12 in manufacturing new light-duty vehicles ceased in the United States and manufacturers of light-duty vehicles uniformly decided to adopt HFC-134a for use in MVAC. Today, while MVAC systems in some older vehicles may still be using CFC-12, HFC-134a remains the dominant refrigerant used in lightduty vehicles worldwide. More recently, additional alternatives for MVAC have been listed as acceptable, subject to use conditions,31 including HFO-1234yf, HFC–152a, and carbon dioxide (CO<sub>2</sub> or R-744). Manufacturers are currently

manufacturing or are actively developing light-duty models using HFO–1234yf, HFC–152a, and CO<sub>2</sub>. The development of MVAC systems using lower-GWP refrigerants has been encouraged by MVAC refrigerant requirements in Europe, where the European Union Directive on Mobile Air Conditioning (MAC Directive) mandates transition to a refrigerant with a GWP below 150 by January 1, 2017,<sup>32</sup> and in the United States by the availability of credits under the Light-Duty Greenhouse Gas (LD GHG) Rule, described in further detail below.

Neither HFC-134a nor any of the refrigerants listed more recently is ozone-depleting. HFO-1234yf, HFC-152a, and CO<sub>2</sub> have much lower GWPs than HFC-134a. HFO-1234yf has a GWP of 4, HFC-152a has a GWP of 124, and CO<sub>2</sub> (by definition) has a GWP of 1 while HFC-134a has a GWP of 1,430. HFC-134a and CO<sub>2</sub> are nonflammable; HFO-1234vf and HFC-152a are flammable. All of the gaseous refrigerants can cause asphyxiation at high concentrations. CO<sub>2</sub> concentrations that could potentially result from refrigerant leaks into the passenger compartment without mitigation measures could reduce a driver's attentiveness and performance. HFC-134a and the three lower-GWP alternatives are exempt from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the national ambient air quality standards. As discussed in the NPRM, EPA has created use conditions for HFC-134a, HFO-1234yf, HFC-152a, and  $CO_2$  that establish unique fittings and labeling requirements, and where appropriate, mitigate flammability and toxicity risks.

HFO–1234yf is being used in cars on the road today in the United States. At the time of the proposal for this rule, EPA was aware that HFO–1234yf was in use in MVAC systems in approximately nine <sup>33</sup> models in the United States produced by several manufacturers of light-duty vehicles. EPA expects, and several commenters indicated that, additional models have or will be introduced using HFO–1234yf systems over the next several years. The results of a 2014 industry survey submitted by

<sup>31</sup> Listed at 40 CFR part 82, subpart G.

<sup>&</sup>lt;sup>32</sup> Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 (EU MAC Directive). This document is accessible at: eur-lex.europa.eu/LexUriServ/ LexUriServ.do?uri=CELEX.32006L0040:EN:HTML.

<sup>&</sup>lt;sup>33</sup> Nelson, 2013. Gabe Nelson. Automakers' switch to new refrigerant will accelerate with EPA credits, European mandate. Automotive News. Available online at www.autonews.com/article/ 20131230/OEM01/312309996/warming-to-the-idea.

AAM and the Association of Global Automakers (Global Automakers) as a public comment to this rule found that automobile manufacturers who responded to the survey had plans in place to transition 90% of light-duty models sold in the United States by or before MY 2021.34 According to comments submitted by Honeywell, there are approximately 28 different automobile brands selling around 60 different models designed to use HFO-1234yf globally.35 DuPont stated that more than 7 million vehicles using HFO–1234yf are estimated to be on the road by the end of 2015 globally, and in addition to infrastructure being in place at vehicle assembly plants, equipment suppliers are already producing the under hood, in factory, and service equipment.36

While EPA was aware in the 1990s that CO<sub>2</sub> might be a feasible alternative in this application, the state of research and development indicated that it was not yet available because a design had not yet been developed that would allow safe use in MVAC systems in light-duty vehicles. More than 20 years later, EPA is still not aware of current commercial use of CO<sub>2</sub> in MVAC systems. However, significant research and development are occurring in order to design a system that will ensure CO2 can be used safely as an MVAC refrigerant. At least one global manufacturer of light-duty vehicles has

announced its intention to commercialize vehicles that use  $CO_2$  as the MVAC refrigerant in the next five years, and perhaps as early as 2016.<sup>37</sup>

In 2008, EPA found HFČ–152a acceptable subject to use conditions. MVAC systems using HFC–152a have not been commercialized to date; however, EPA is aware of a demonstration project in India with a major Indian motor vehicle manufacturer considering HFC–152a in secondary loop MVAC systems.<sup>38</sup>

In addition to the use and development of HFO–1234yf, HFC–152a, and CO<sub>2</sub> MVAC systems, EPA is aware of ongoing research and development which could ultimately result in future listings of additional alternatives for light-duty MVAC systems. For example, since the publication of the proposed rule, the SNAP program received a new submission for another low-GWP alternative that is a blend with a GWP below 150.

There are also several blend refrigerants that have been listed as acceptable or acceptable, subject to use conditions, since 1994, but that have never been developed for use in MVAC or used in manufacture of new vehicles. Today's action will change the status of these refrigerant blends to unacceptable as of MY 2017 for use in newly manufactured light-duty vehicles. These substitutes include HFC blends SP34E

and R–426A (also known as RS-24) with GWPs of 1,380 and 1,508, respectively, and the HCFC blends, R–416A (also known as HCFC Blend Beta or FRIGC FR12), R–406A, R–414A (also known as HCFC Blend Xi or GHG–X4), R–414B (also known as HCFC Blend Omicron), HCFC Blend Delta (also known as Free Zone), Freeze 12, GHG-X5, and HCFC Blend Lambda (also known as GHG-HP), with GWPs ranging from 1,480 to 2,340 and ODPs ranging from 0.012 to 0.056. For simplicity, we refer to these substitutes as "the refrigerant blends" in the following discussion.

As noted above, none of these are currently used by the original equipment manufacturers (OEMs) nor are we aware that any models are being developed for use with these substitutes. All of these refrigerant blends have GWPs that are significantly higher than the GWPs for HFO–1234yf, HFC–152a, and  $\rm CO_2$  and the blends containing HCFCs have ODPs ranging from 0.012 to 0.056. As discussed, there are alternatives with lower overall risk to human health and the environment that are available for this use.

2. What is EPA finalizing regarding MVAC systems for newly manufactured light-duty motor vehicles?

The change of status determinations for MVAC are summarized in the following table:

TABLE 3—CHANGE OF STATUS DECISIONS FOR MVAC

End-use	Substitutes	Decision
Motor vehicle air conditioning (new equipment in passenger cars and light-duty trucks only).	HFC-134a	Unacceptable as of Model Year (MY) 2021, except where allowed under a narrowed use limit through MY 2025. Acceptable, subject to narrowed use limits, for vehicles exported to countries with insufficient servicing infrastructure to support other alternatives, for MY 2021 through MY 2025; Unacceptable for all newly manufactured vehicles as of MY 2026.
Motor vehicle air conditioning (new equipment in passenger cars and light-duty trucks only).	R-406A, R-414A (HCFC Blend Xi, GHG-X4), R-414B (HCFC Blend Omicron), HCFC Blend Delta (Free Zone), Freeze 12, GHG- X5, HCFC Blend Lambda (GHG-HP), R- 416A (FRIGC FR-12, HCFC Blend Beta), SP34E, R-426A (RS-24, new formulation).	Unacceptable as of MY 2017.

# (a) HFC-134a

In the August 6, 2014, proposal, EPA proposed to change the listing status of HFC–134a from acceptable to

unacceptable for use in air conditioning systems in newly manufactured passenger cars and light-duty trucks beginning in MY 2021.<sup>39</sup> This final action adopts the proposed approach,

but with one exception. Specifically, we are including a narrowed use limit for HFC–134a in MVAC systems of newly manufactured passenger cars and lightduty trucks destined for use in countries

<sup>&</sup>lt;sup>34</sup> EPA–HQ–OAR–2014–0198–0207 and EPA– HQ–OAR–2014–0198–0113.

 $<sup>^{35}\,\</sup>mathrm{EPA}$  – HQ – OAR – 2014 – 0198 – 0170.

<sup>&</sup>lt;sup>36</sup> EPA-HQ-OAR-2014-0198-0077.

<sup>&</sup>lt;sup>37</sup> Daimler, 2014.

<sup>&</sup>lt;sup>38</sup> Andersen et al., 2015. "Secondary Loop Motor Vehicle Air Conditioning Systems (SL–MACs). Using Low-Global Warming Potential (GWP) Refrigerants in Leak-Tight Systems In Climates with High Fuel Prices and Long, Hot and Humid Cooling Seasons. Building on the Previous Success of

Delphi, Fiat, General Motors, Volvo, Red Dot, SAE Cooperative Research Projects, And Other Engineering Groups.'' MACS Briefing, 2015.

<sup>&</sup>lt;sup>39</sup> Because the MVAC system used is so closely related to vehicle design, we are using model years and not calendar years.

that do not have infrastructure in place for servicing with other acceptable refrigerants. This narrowed use limit will be in place through MY 2025.

This change of status applies to MVAC systems for passenger cars and light-duty trucks as defined at 40 CFR 86.1803–01, referred to jointly in this FRM as light-duty vehicles. As discussed in the NPRM and above, three alternatives currently on the SNAP list of substitutes that are acceptable, subject to use conditions—HFC-152a, CO<sub>2</sub>, and HFO-1234yf-are in use or under various stages of development and have significantly lower GWPs than HFC-134a. Use conditions for these substitutes mitigate flammability and toxicity risks, as relevant, and thus for the other factors EPA evaluates, there was not an appreciable difference in risk. Because HFC-134a has a significantly higher GWP than HFC-152a, CO<sub>2</sub>, and HFO-1234yf, and because the use conditions for these three refrigerants ensure that other risks are not appreciably higher than for HFC-134a, we are listing HFC-134a as unacceptable for use in MVAC systems in new light-duty vehicles in MY 2021.

Without the use conditions these other substitutes do not pose overall lower risk than HFC-134a. Thus, in deciding when the unacceptability determination should apply, we considered when it would be feasible for manufacturers to develop systems meeting the use conditions. We proposed MY 2021 while also requesting comment on MY 2017, MY 2019 and MYs later than 2021. As explained in the NPRM, EPA considers MY 2021 the date by which automobile manufacturers will be able to redesign all vehicle models (including design of the MVAC systems) for use with a lower-GWP alternative, consistent with the use conditions.

EPA previously considered the model year by which manufacturers of lightduty vehicles would be able to transition away from use of HFC-134a in support of the greenhouse gas and fuel economy standards for MY 2017-2025 light-duty vehicles issued jointly by EPA and NHTSA on August 28, 2012.40 As part of that rulemaking, EPA established the availability of credits for the use of alternative refrigerants with lower GWPs than that of HFC-134a towards meeting the LD GHG standards. For today's action, EPA relied on the analysis conducted in support of the LD GHG standards for MYs 2017-2025. The

analysis considered the practices used by the automobile manufacturing industry in introducing new technologies into their vehicles through manufacturing redesign changes and refresh cycles. For each vehicle model, manufacturers establish a product development cycle over which they plan any significant technological changes or "redesigns" to that vehicle. Between the major redesign model years, they may make only minor "refresh" changes.41 At any point in time, a manufacturer may have some vehicles at or approaching a major redesign point and others that are earlier

in their product cycle.

In developing the LD GHG standards, EPA assumed that the transition to alternative refrigerants would generally need to occur during manufacturer model redesigns because of changes to the system design that are needed to allow the safe use of these alternatives consistent with the regulatory use conditions.<sup>42</sup> EPA used the overall typical industry redesign cycle of five model years to estimate how the expected industry-wide transition to new refrigerants might occur. Thus, EPA projected that the industry, in order to safely make use of the credits offered for use of lower-GWP refrigerants, would fully transition to these refrigerants over the time between MY 2017 and MY 2021, beginning with 20 percent transition in MY 2017, to be followed by a 20 percent increase in substitution in each subsequent model year, completing transition in MY 2021.43 EPA continues to rely on the projections made in support of the LD GHG Rule as well as all other information currently available to the Agency to support the decision in this action that MY 2021 is the MY by which it will be feasible for manufacturers to safely, but expeditiously, transition MVAC systems for all light-duty vehicle models.

EPA proposed to modify the listing of HFC–134a to unacceptable as of MY 2021 for light-duty vehicles, and sought comment on MYs 2017, 2019, and MYs later than 2021. Some commenters argued that full transition cannot occur until after MY 2021 because a limited number of models do not currently have plans in place to transition by MY 2021. For these models, commenters claimed that two full design cycles, which could take 10 years, will be necessary in order

to transition. Commenters also provided information that the vehicle redesign is not "locked-in" until two years before the model year. EPA understands that because MY 2016 vehicles are being produced in the 2015 calendar year, this means most manufacturers have "locked-in" their planned product designs for MY 2016 and MY 2017, or potentially even out to MY 2018.44 EPA did not receive information on why manufacturers cannot redesign models that are not yet locked-in or why MVAC system redesign cannot occur during a product refresh for those models that are locked-in. According to the 2014 survey of the automobile industry, manufacturers who participated in the study indicated that they already expect to have transitioned 90% of the fleet by MY 2021. We did not receive any information indicating it was not technically feasible to also transition the remaining 10% of models by MY 2021.

EPA expressly requested specific information supporting claims that a transition by MY 2021 would not be technically feasible because specific model vehicles cannot be redesigned to safely use alternative refrigerants by MY 2021. No such information was forthcoming. Although one manufacturer did provide information on the increase in cost to transition for a particular type of vehicle that was originally not planned for a refrigerant change by MY 2021,45 commenters did not submit specific information, confidential or otherwise, that showed it would not be technically feasible for any specific model vehicles to adjust their redesign cycle, switch refrigerants mid-cycle, or switch during a refresh. After thoroughly reviewing all of the information in the possession of the Agency, EPA did not find a technical basis for extending the change of status date beyond MY 2021. We believe the information in the record supports a conclusion that it is feasible for vehicles and the associated MVAC systems to be redesigned to safely use alternative refrigerants by MY 2021.

EPA also received comments on this rule requesting an earlier change of

<sup>40 77</sup> FR 62624, 62807-810 (October 15, 2012); see also 75 FR 25325, 25431-32 (May 7, 2010) (discussing the same issue for MY 2012-2016 lightduty vehicles)

<sup>&</sup>lt;sup>41</sup> See 77 FR 62712 and 75 FR 25407, 25451 for a more detailed discussion of this practice.

<sup>42</sup> As previously noted, HFO-1234vf, CO2 and HFC-152a are all listed as acceptable subject to use conditions and many of the use conditions address the design of systems to account for flammability or exposure.

<sup>&</sup>lt;sup>43</sup> 77 FR 62720.

<sup>&</sup>lt;sup>44</sup> Global Automakers, in their comments on the NPRM, stated, "These major model re-designs typically occur every five or six model years, and are staggered year-by-year so that the manufacturer's full product line is refreshed over time rather than all at once. Because of the need to lock in suppliers to support production well in advance, vehicle designs are usually locked in about two years before the model year." EPA-HQ-OAR-2014-0198-0207.

 $<sup>^{45}</sup>$  As explained in more detail in the responses to comments, under the SNAP criteria for review in 40 CFR 82.180(a)(7), the only cost information that EPA considers as part of its SNAP review is the "cost and availability of the substitute."

status date based on the availability of alternative refrigerants and the fact that transition is already occurring in the United States and globally. The available information indicated that many of the models that have already transitioned are being sold in Europe rather than in the United States. There is no information showing that it is technically feasible for all or most models to transition to alternatives safely by MY 2017 or MY 2019, which begin in 2016 and 2018 respectively. As discussed below in the responses to comments, MY 2021 is the earliest year that we find provides sufficient time to transition refrigerant during vehicle redesign cycles or to plan a mid-cycle transition to alternatives that ensures safety through compliance with SNAP use conditions.

We also considered the supply of the alternative refrigerants in determining when alternatives would be available. At the time the light-duty GHG rule was promulgated, there was a concern about the potential supply of HFO-1234yf. Some commenters indicated that supply is still a concern, while others, including two producers of HFO-1234yf, commented that there will be sufficient supply. Moreover, some automotive manufacturers are developing systems that can safely use other substitutes, including CO2, for which there is not a supply concern for the refrigerant. If some global light-duty motor vehicle manufacturers use CO<sub>2</sub> or another acceptable alternative, additional volumes of HFO-1234yf that would have been used by those manufacturers will then become available. Based on all of the information before the Agency, EPA believes production plans for the refrigerants are in place to make available sufficient supply no later than MY 2021 to meet current and projected demand domestically as well as abroad, including, but not limited to, the EU.

Based on information the Agency possessed at the time of the proposal and additional information submitted during the comment period regarding the technical feasibility of transitioning the fleet of light-duty vehicles and refrigerant supply, we conclude that MY 2021 represents the time by which other alternative refrigerants that pose less overall risk than HFC-134a can be used in all light-duty vehicle models consistent with the use conditions. Thus, MY 2021 is the time at which those alternative refrigerants will be "available" within the meaning of CAA section 612(c)(2).

#### (b) Refrigerant Blends

In today's action, EPA is also finalizing changes to the listing status of SP34E, R-426A, R-416A, R-406A, R-414A (also known as HCFC Blend Xi or GHG-X4), R-414B (also known as HCFC Blend Omicron), HCFC Blend Delta (also known as Free Zone), Freeze 12, GHG-X5, and HCFC Blend Lambda (also known as GHG-HP) from acceptable to unacceptable for use in newly manufactured light-duty motor vehicles beginning in MY 2017, as proposed. The GWPs of HFC-152a, HFO-1234vf, and CO2 are significantly lower than those of the refrigerant blends and all but two of these blends have ODPs, whereas HFC-152a, HFO-1234vf, and CO<sub>2</sub> do not. Moreover, if used consistent with the established use conditions, the three lower-GWP refrigerants do not pose greater overall risk than any of the refrigerant blends. At the time of the proposal, EPA was not aware of current or projected future use of these refrigerant blends in any MVAC systems in newly manufactured light-duty vehicles. We did not receive any comments providing information suggesting current or projected use of these refrigerant blends in any newlymanufactured light-duty MVAC systems and received several comments supporting this aspect of the proposal. EPA is changing the listing status for the refrigerant blends to unacceptable for use in new light-duty vehicles as of MY 2017, the next model year in production after this rule is issued.

#### 3. MVAC Servicing

EPA did not propose and is not making any changes that would alter the ability to service existing motor vehicles designed to use HFC–134a or a refrigerant blend.<sup>46</sup>

MVAC systems designed to use lower-GWP substitutes and installed in vehicles will need to be serviced. Some stakeholders and commenters have expressed a concern that the price differential between HFO-1234yf and HFC-134a provides an economic incentive to replace HFO-1234yf with HFC-134a during servicing.47 HFC-134a is listed, and will remain listed, as an acceptable refrigerant for retrofit of existing systems designed to use CFC-12, but because of the use restrictions for refrigerants listed as acceptable, it cannot be used as a retrofit for MVAC systems using other alternatives. Specifically, the SNAP listings for all MVAC refrigerants require the use of

unique fittings for each alternative refrigerant. These fittings are found at attachment points on the car itself, on all recovery and recycling equipment, on can taps and other charging equipment, and on all refrigerant containers. The purpose of these fittings is to prevent cross-contamination. Using an adapter or deliberately modifying a fitting to use a different refrigerant is a violation of these use conditions. If used properly, the unique fittings will not allow for the introduction of HFC-134a refrigerant to an HFO-1234yf system. Furthermore, the SNAP regulations prohibit using a substitute refrigerant to 'top-off' a system that uses another refrigerant and the SNAP use conditions for refrigerants in this end-use require that the original refrigerant be recovered, in accordance with regulations issued under section 609 of the CAA, prior to charging with a substitute (40 CFR 82.34). Thus, the SNAP use conditions prohibit adding a new refrigerant to the system without first recovering the refrigerant already in the system.

For vehicles for which the manufacturer counts air conditioning credits toward its LD GHG compliance, the MVAC systems (or elements of those systems) are considered emissionrelated components as defined in 40 CFR 86.1803. This designation includes provisions for emission-related warranty, requirements that they operate properly for the specified useful life, as well as tampering restrictions. For example, if a manufacturer claims air conditioning credits for an MVAC system that uses a lower-GWP refrigerant on a particular vehicle as part of the LD GHG program, removing and replacing that refrigerant with any other refrigerant that has a higher GWP, including HFC-134a, would be considered tampering with an emissionrelated component under Title II of the CAA.

# 4. Would this action affect EPA's LD GHG Rule?

In their comments, AAM stated that "EPA should state clearly and unequivocally in the final rule that EPA is committed to continuing the A/C credits through MY 2025 and beyond." Global Automakers made a similar request. EPA in fact stated in the NPRM, and reiterates here, that nothing in this final rule changes the regulations establishing the availability of air conditioning refrigerant credits under the GHG standards for MY 2017-2025, found at 40 CFR 86.1865-12 and 1867-12. Those standards and credits are established by rule and EPA did not reopen that rule in this proceeding.

 $<sup>^{\</sup>rm 46}\,\rm EPA$  is also clarifying that thermostatic expansion valves (TXVs) are not impacted by today's action.

<sup>&</sup>lt;sup>47</sup> See also 77 FR 62807.

Thus, manufacturers can generate credits from use of lower-GWP alternative refrigerants through MY 2025, and the ability to generate and use those credits towards compliance with the LD GHG standards will not change under this final rule. 48 We do note further, however, that the LD GHG standards do not require any specific means of compliance, so that manufacturers have the flexibility to either switch refrigerants or to comply with the standards by other means. If a manufacturer chooses to comply with the LD GHG standard by a strategy not involving refrigerant substitution, for MY 2021 and later vehicles, this final rule would still require the manufacturer to use refrigerant other than HFC-134a.

5. How will the change of status apply to exports of MVAC systems?

# (a) SNAP Interpretation

Under 40 CFR 82.174, no person may introduce a refrigerant substitute into interstate commerce without notifying EPA 90 days in advance. Our longstanding interpretation of this regulatory provision is that the notification requirement applies to products manufactured in the United States and exported. EPA has defined interstate commerce in our labeling regulations at 40 CFR 82.104(n) as: "The distribution or transportation of any product between one state, territory, possession or the District of Columbia, and another state, territory, possession or the District of Columbia, or the sale, use or manufacture of any product in more than one state, territory, possession or the District of Columbia. The entry points for which the product is introduced into interstate commerce are the release of a product from the facility in which the product was manufactured, the entry into a warehouse from which the domestic manufacturer releases the product for sale or distribution, and at the site of United States Customs clearance.' While this definition appears in EPA's labeling regulations, EPA's practice is to use it for purposes of the SNAP program as well. See e.g., 76 FR 78846, December 20, 2011 ("This definition applies to any appliances produced in the United States, including appliances that will be exported.")

In addition, under the SNAP regulations EPA regulates "use" in the United States and "use" is defined at 40 CFR 82.172 to include "use in a manufacturing process or product, in consumption by the end user, or in

intermediate uses, such as formulation or packaging for other subsequent uses." Charging a MVAC system with refrigerant during the manufacturing of a vehicle in the United States is considered a "use" under the SNAP program. This is consistent with our statement in the initial SNAP rule that "Substitutes manufactured within the U.S. exclusively for export are subject to SNAP since the definition of use in the rule includes use in the manufacturing process, which occurs within the United States." (59 FR 13052; March 18, 1994)

# (b) Narrowed Use Limit for MVAC

Based on comments received, we understand that certain countries to which vehicles are exported do not, and may not for some period of time, have in place the infrastructure for servicing MVAC systems with flammable refrigerants. Because this raises concerns with the safe usage of HFC-152a and HFO-1234yf, we have determined that there may be circumstances in which alternatives that pose lower overall risk to human health and the environment will not be available for MVAC systems in those vehicles by MY 2021. Therefore, EPA is providing a narrowed use limit for MVAC systems that applies to vehicles being exported to countries that do not have infrastructure to service vehicles containing the alternatives found to pose less overall risk.

Under a narrowed use limit, the manufacturer needs to ascertain that these other alternatives are not technically feasible because of the lack of infrastructure for servicing with the alternative refrigerants and document the results of their analysis. See 40 CFR 82.180(b)(3). Users are not required to report the results of their investigations to EPA, but must retain the documentation in their files for the purpose of demonstrating compliance.

Documentation should include descriptions of:

- Products in which the substitute is needed;
- Substitutes examined and rejected for the destined country;
- Reason for rejection of other alternatives; and
- Anticipated date other substitutes will be available and projected time for switching.

Based on the comments received, EPA does not anticipate that a significant number of countries will lack the necessary infrastructure needed to service MVAC systems with the alternatives for which the equipment is designed by MY 2021. Also, based on the comments received, we do not believe that an extensive additional

amount of time will be needed before the necessary infrastructure is in place. Therefore, under this final rule, the narrowed use limit will no longer be available beginning with MY 2026 vehicles.

6. How is EPA responding to comments concerning this end-use?

## (a) Timeline

Comment: EPA received several comments on the current and projected pace of adoption of alternative refrigerants. Several commenters stated that transition to HFO-1234yf is already occurring. Honeywell commented that there are approximately 28 different automobile brands selling around 60 different models designed to use HFO-1234yf globally and that more than a dozen models are being manufactured by U.S. manufacturers. Other commenters provided similar statistics. One of these commenters, DuPont, estimated that globally, more than 7 million vehicles using alternatives other than HFC-134a will be on the road by the end of 2015. They also commented that in addition to infrastructure being in place at vehicle assembly plants, equipment suppliers are already producing the under-hood, in-factory, and service equipment necessary for the transition.

AAM and Global Automakers "conducted an industry survey to create a 'non-confidential' blinded summary of individual manufacturer refrigerant changeover plans." <sup>49</sup> Ten automobile manufacturers, representing 85% of light-duty vehicles sold in the United States in MY 2013, submitted information. The survey found that out of 139 vehicle platforms, manufacturers currently plan to transition 90% of the models by MY 2021.

Response: EPA recognizes some manufacturers have already transitioned to use of HFO-1234yf in a limited number of models. In the United States the transition began in a small number of MY 2013 vehicles, and increased in MY 2014  $^{50}$  and MY 2015. As of the beginning of 2015, the U.S. fleet was continuing on a trajectory that we expect to achieve 20% adoption by MY 2017, which aligns with EPA's projection in the supporting documents for the light-duty GHG rule.51 While adoption is occurring in the United States, most of the estimated 7 million vehicles mentioned by DuPont are in Europe where the EU MAC Directive

<sup>48</sup> See 77 FR 62804–809.

<sup>&</sup>lt;sup>49</sup> EPA–HQ–OAR–2014–0198–0207 and EPA– HQ–OAR–2014–0198–0113

<sup>&</sup>lt;sup>50</sup> Nelson, 2013.

<sup>&</sup>lt;sup>51</sup> 77 FR 62720.

mandates transition to refrigerant with a GWP below 150 by January 1, 2017.

The Agency recognizes and appreciates the factual information supplied by the commenters, including the information shared as a result of the 2014 industry-led survey conducted by AAM and Global Automakers. EPA's responses to the comments submitted by AAM and Global Automakers within the context of the survey are provided below. EPA relied on all of the information in our possession as we made our decision on the change of status for HFC–134a.

Comment: Several commenters noted that the transition from CFC-12 to HFC-134a was achieved in about three to four model years and claimed that the transition from HFC-134a to lower-GWP alternatives could also happen in the same timeframe.

Response: Regarding the comments suggesting that the current transition could occur in a similar period of time to the transition from CFC–12 to HFC–134a for MVAC, EPA disagrees because the system changes required for this transition are more extensive than those required for the transition from CFC–12 to HFC–134a. It is EPA's understanding, as confirmed by comments, such as those from the automobile associations, that many models will need to transition during a redesign cycle.

EPA understands that many model types will require hardware changes that normally occur during a redesign, unlike the transition from CFC-12 to HFC-134a. HFO-1234yf has a slightly lower cooling efficiency than that of HFC-134a; offsetting this efficiency difference usually requires hardware changes, specifically the incorporation of an internal heat exchanger and potentially other system adjustments, which in some cases could result in changes to overall air conditioning system design and layout. CO<sub>2</sub> MVAC systems will require significantly more hardware changes, which in many cases is expected to result in changes to the system design and layout. This transition contrasts with the case of the transition in the 1990s from CFC-12 to HFC-134a, where the systems did not require changes to the components of the MVAC system, besides the fittings, allowing manufacturers to switch many vehicles mid-cycle. Some models were already being manufactured using HFC-134a as early as 1992, with a significant proportion already being manufactured with HFC–134a by the time that EPA listed it as acceptable in the initial SNAP rule (59 FR 13044; March 18, 1994).

Comment: EPA received several comments related to the proposed time

for changing the listing status of HFC-134a in MVAC. Several commenters support accelerating the proposed transition to earlier than MY 2021, and recommended implementation dates of MYs 2017, 2018, and 2019. Many cited the progression of transition in the EU, as well as the transition already seen in the United States as a result of EPA's LD GHG Rule in support of an earlier transition timeframe. Honeywell, a producer of HFO-1234yf, commented "that given manufacturers' experience in the EU and United States there is already an understanding and capability to transition vehicles for U.S. car production" and they recommended a transition date of MY 2018. DuPont, another producer of HFO-1234yf, stated "there are no technology, supply or engineering barriers to rapid transition" and recommended a transition date of MY 2019. EIA commented that there is no reason to delay the change in status and recommended MY 2017 as the implementation date. Two commenters, NRDC and IGSD, jointly commented that EPA should adopt MY 2017, a deadline that would be set based on the leaders in the industry that are already using safer chemicals, rather than the laggards. Effective Altruism at the University of Maryland commented that HFC-134a should be listed as unacceptable as of January 2017, and the California Air Resource Board (CARB) commented that MY 2018 is a reasonable timeframe for the unacceptable listing to apply.

Some commenters stated that aligning with the EU transition by January 1, 2017, will signal to the international community that the United States is taking steps to "promote the rapid deployment of climate-friendly and safe alternatives in motor vehicle air conditioning" as agreed to in the Leaders' statement at the G-7 Summit in June 2014. Some commenters suggested an accelerated transition date is needed to achieve the President's environmental goals, and would have a significant trickle-down effect in other markets around the world, specifically commenting that selecting MY 2017 would encourage Japan to "set the same global motor vehicle air-conditioning phaseout schedule for HFC-134a." Also, NRDC and IGSD commented that "matching the MY 2017 European schedule is protecting against American automakers finding themselves unprepared when other markets close their doors to automobiles made with HFC-134a." Some commenters stated that the transition can be achieved by an earlier date and that greater environmental benefits would be

achieved with an earlier transition. These commenters stated that MY 2021 would not provide benefits beyond those achieved under "business as usual."

Response: EPA agrees with the commenters that suggested that an earlier transition year would result in greater environmental benefits to the extent that it would result in earlier reduction of use of HFC-134a in MVAC. However, in considering whether other listed alternatives are available that pose lower overall risk, EPA needs to consider whether there are any technical challenges that would prevent use of those alternatives consistent with the use conditions which are necessary to ensure that they pose lower risk than HFC-134a. EPA does not agree that a safe, smooth transition in compliance with the use conditions required for the lower-GWP alternatives can be made for all vehicles prior to MY 2021 in the United States. This is based on the need to transition most vehicles during redesign cycles, which in many cases requires hardware changes, as discussed above. EPA has also considered the potential benefits to aligning our domestic transition to the EU's, in light of the fact that the transition to MVAC systems using one of the three alternatives began earlier than we predicted, and in light of the adequate supply of alternatives. Based on our current understanding and the information provided by commenters, especially the automobile manufacturers, the Agency has concluded that MY 2021 is the earliest date by which all model vehicles can be safely transitioned to lower-GWP alternatives in accordance with the use conditions.

We note that even though we are establishing MY 2021 as the date by which HFC-134a will be unacceptable,52 EPA expects health and safety benefits will be realized sooner, as manufacturers will be designing new models each year using lower-GWP refrigerants for MVAC. The benefits analysis provided with the NPRM (EPA, 2014) and the analysis associated with this final action (EPA, 2015b) use a "business as usual" scenario that assumes a transition in refrigerant for MVAC will occur for vehicles manufactured and sold in the United States, in order to be consistent with the LD GHG Rule, and that assumes no regulatory action, and thus no benefits, under SNAP. However, our analysis of

<sup>&</sup>lt;sup>52</sup> As noted elsewhere, we are creating a narrowed use limit for vehicles exported to countries without adequate facilities for servicing vehicles with the other acceptable alternatives.

the effects of a change of status for MVAC as of MY 2021 shows some benefits beyond the "business as usual" scenario, reflecting the use of lower-GWP refrigerants in exported vehicles.

While not relevant to EPA's decision regarding the appropriate date for changing the status of HFC–134a for use in MVAC, EPA also agrees its action to change the status of HFC–134a will send a valuable signal to the international community regarding the continued use of high-GWP alternatives.

Comment: NRDC and IGSD suggested that EPA set a status change date as of MY 2017, and address any sub-sectors that have problems meeting a transition date earlier than MY 2021 through a narrowed use limit. EIA recommended transition in MY 2017 and suggested EPA grant a limited exemption until MY 2021 for companies who publicly pledge to convert to CO<sub>2</sub> systems.

Response: EPA is not finalizing today's rule with a change of status for HFC-134a as of MY 2017, as recommended by these commenters. As discussed above, it is our understanding that because of the necessary changes to hardware, manufacturers will need to transition most vehicles during a redesign cycle. Although in some cases where less extensive hardware changes are required, it will be possible to transition mid-cycle, it is not reasonable to expect that most manufacturers will be able to do so. Achieving a transition by MY 2017, approximately one year from now, would not be feasible for any manufacturers that had not already started transition planning before issuance of the NPRM, and in such a circumstance, we do not consider it reasonable to require compliance based on actions that would have been necessary before issuance of the NPRM. Rather than setting a change of status date that we expect manufacturers may have difficulty meeting, we are setting the change of status date at the earliest model year by which the best information indicates that all model vehicles can be safely transitioned to lower-GWP alternatives in accordance with the use conditions.

Concerning EIA's suggestion for a limited exemption until MY 2021 for companies who publicly pledge to convert to  $CO_2$  systems, because we have set MY 2021 as the status change date for all vehicles, there is no need for an exemption related to adoption of  $CO_2$  MVAC systems.

Comment: A private citizen commented in support of a MY 2021 change of status.

Response: EPA is finalizing a MY 2021 transition date for the reasons previously stated.

Comment: Several commenters supported transition in MY 2025 or later, including AAM, Global Automakers, NADA and Mexichem. The majority of these commenters stated that reengineering and system design requirements for alternative refrigerants require significant lead time and necessitate transition during a vehicle redesign cycle. Commenters stated that two full design cycles lasting beyond MY 2021 may be necessary in order to complete the transition due to timing of publication of the proposed status change rule, and the relationship of that to where manufacturers are in the redesign cycle for each model. Global Automakers commented that the vehicle redesign cycle is usually locked in about two years before the model year. Commenters supporting a transition date of MY 2025 or later also commented that a later date would align with the existing LD GHG Rule with no measurable environmental impact at stake, and address supply concerns. With regard to the 10% of vehicle platforms identified in the 2014 industry survey as planning to transition after MY 2021, AAM, and Global Automakers commented that those are not all small volume platforms and the production will account for a small, but not insignificant percentage of production after MY 2021.

Response: Regarding comments by AAM, Global Automakers, and Mexichem suggesting that two full design cycles, extending past MY 2021, would be needed to transition all vehicle models to alternative refrigerants, the commenters failed to provide any specific, technical support for such a claim. EPA appreciates the submission of 2014 survey data indicating that automobile manufacturers have plans in place to transition 90% of vehicle models to alternative refrigerants by MY 2021. However, the commenters did not provide support or an explanation of why it will not be technically feasible to transition each of the remaining individual models by MY 2021. According to commenters, the vehicle redesign is locked in two years before the model year; therefore, time still exists to make the necessary alterations to MY 2017, MY 2018 and later vehicles. While we believe it would be possible for the majority of models to transition by MY 2021 during a redesign cycle, EPA is aware that sometimes it is technically feasible to transition between redesign cycles during a midcycle redesign, or refresh. A manufacturer shared with EPA information claimed as confidential that

more than one vehicle model in the United States has been transitioned to HFO–1234yf, in compliance with the SNAP use conditions, between scheduled redesign cycles. Although it would not be feasible to expect most models to transition mid-redesign cycle, for such a small number of models, this is likely to be feasible. EPA did not receive any information that provides specific and sufficient information to show that transition by MY 2021 is not technically feasible for any specific model vehicle. One automobile manufacturer provided information claimed as confidential concerning vehicles used for a specific purpose but did not provide sufficient justification that transition by MY 2021 was not feasible for technical reasons. EPA is aware of two automobile manufacturers that will have the majority of their U.S. fleet transitioned by MY 2016. EPA is also aware of several automobile manufacturers intending to transition all of their vehicle models by MY 2021.

While the AAM and Global Automakers survey does not indicate the impetus for the transition plans for the various manufacturers and models, EPA assumes the plans were adopted in response to the credits offered under EPA's LD GHG Rule. EPA further assumes these transition plans were based on strategic utilization of credits available under the rule as a flexibility measure, rather than technical feasibility of transition, and EPA did not receive any information to the contrary.

Comment: AAM stated that a MY 2025 transition date would accommodate "run-out" models. "Run-out" models are defined as models that, for a variety of reasons, will continue to be produced and marketed without any updates to major vehicle sub-systems, including AC systems. Commenters indicated that to require an early end of production for such run-out models would increase the levels of stranded investment associated with ending the production of such models prematurely.

Response: Commenters did not indicate what portion of the vehicle models with current plans to transition in MYs after 2021 is made up of "runout" models, if any, as compared to other models captured in the results of the industry survey. In the proposed rule, EPA requested comment on changing the status of HFC-134a in a MY later than 2021, "including specific information supporting claims that a transition by MY 2021 would not be technically feasible because specific model vehicles cannot be redesigned to safely use alternative refrigerants by MY 2021." EPA did not receive this type of

information. EPA is not aware of any technical barriers that preclude transition of "run-out" models by MY 2021 given the time available between now and MY 2021 to implement a transition for these models.

Comment: Commenters indicated the challenges associated with designing MVAC systems to use alternative refrigerants, especially CO<sub>2</sub>. AAM provided information on the hardware changes and component supply, as well as industry standards needed for MVAC systems to use CO<sub>2</sub>. AAM commented that "a MY 2025 date would allow extra time for commercialization of CO<sub>2</sub> MVACs."

Response: EPA is aware that CO2 systems require significantly more complex redesign and hardware development than HFO-1234yf systems, primarily because the operating pressures of these systems will be significantly higher than that of a HFC-134a system. Therefore, EPA understands that incorporation of CO<sub>2</sub> MVAC systems would most likely need to occur during product redesign, not product refresh. At least one manufacturer has stated that it plans on using CO<sub>2</sub> systems. These systems are currently in prototype phase, and we understand that there may be significant technical hurdles yet to overcome. However, those pursuing this option have announced plans to introduce cars in Europe with CO<sub>2</sub> MVAC systems as early as MY 2017. This timing allows for several years after initial deployment of these systems for automobile manufacturers to redesign models prior to the MY 2021 date in the United

Given the transition plans in place, EPA disagrees that other alternatives, including CO<sub>2</sub>, cannot be used consistent with the use conditions by MY 2021. However, even if a particular alternative could not be used in some or any vehicles consistent with the use conditions by MY 2021, for the reasons already provided, we have determined that other alternatives can be safely used consistent with the use conditions by MY 2021. Because alternatives that pose lower risk than HFC-134a will be available by MY 2021, we do not believe there is a basis for selecting a later date for changing the status of HFC-134a.

Comment: AAM raised concerns about the transition of manufacturing facilities and the need to modify or upgrade refrigerant storage facilities and charging stations on assembly lines. Also, the commenters stated that because many manufacturing facilities produce multiple vehicle models, some plants may not have the space necessary

to accommodate infrastructure for both refrigerants.

Response: EPA understands that there are challenges associated with transitioning refrigerants. EPA is also aware that prior to issuance of the NPRM, manufacturers were planning a gradual, model-by-model transition, in which some models would be filled with HFC–134a while others are filled with HFO–1234yf or another alternative refrigerant at the same plant.

Comment: In the proposed rule EPA requested specific information supporting claims that a transition by MY 2021 would not be technically feasible because specific model vehicles cannot be redesigned to safely use alternative refrigerants by MY 2021. AAM commented stating that "EPA did not properly consider confidentially submitted information that alternatives will not be available until after MY 2021."

Response: EPA has considered information provided to the Agency and claimed as confidential as support for this and other decisions that are part of this action. As described elsewhere in this section, EPA did not receive sufficient information, whether claimed confidential or not, to conclude that other alternatives cannot be used consistent with their use conditions by MY 2021.

Comment: Many commenters provided comments about the impact the supply of acceptable alternatives could have on the timeline for transition. Several commenters believe there is enough supply of alternatives to transition prior to MY 2021.

The comments submitted by Honeywell and DuPont, current suppliers of HFO-1234yf, indicate that both companies are confident in their ability to supply enough HFO-1234yf to support a full transition by MY 2018 and MY 2019, respectively. According to comments submitted by Honeywell "there is one commercial scale HFO-1234yf production plant operating today in China, a second one is expected to be commissioned in the first half of 2015 in Japan via a strategic supply relationship between Honeywell and Asahi Glass Company Ltd, and a third world-scale plant will be commissioned by Honeywell by the end of 2016 in Geismar, Louisiana." DuPont submitted similar comments on announced or planned production capacity in Asia, the United States and Europe by multiple producers, including DuPont, Honeywell, and Asahi Glass Co. (AGC), indicating that production will begin in 2015–2017 at most of these facilities.

CARB commented that they understand that chemical manufacturers

expect to be capable of providing a sufficient supply of HFO–1234yf for complete U.S. transition away from HFC–134a starting with MY 2018. In support of a MY 2017 transition date, NRDC and IGSD commented that the supply of alternatives (HFO–1234yf and others) is not a constraint; they believe EPA correctly recognizes that "production plans for the refrigerant appear to be in place to make it available in volumes that meet current and projected domestic auto industry demand."

Response: EPA appreciates information provided by commenters supporting EPA's understanding at the time of the proposal that sufficient supply will be available to support a transition in MY 2021. The companies producing HFO-1234vf commented that sufficient supplies should be available for MY 2018 or 2019, indicating that there will be sufficient supplies prior to MY 2021. In addition, the commenter submitted additional information to the Agency that they claimed as confidential and that further supports that adequate supply will be available by MY 2021.

Comment: Several commenters supported MY 2025 or later, expressing concerns about ongoing uncertainty in sufficient supply of HFO-1234yf for a full U.S. transition by MY 2021 due to limited production, as well as lack of competition, artificial constraints, and other factors. Arkema commented that they estimate the global demand for HFO-1234yf in 2021 will be around 45,000 metric tons and they believe Honeywell and DuPont will only be able to supply half that amount. Arkema commented that the supply shortage would cause a serious dislocation in supply and demand (*i.e.*, willing buyers would be unable to find willing sellers of HFO-1234yf) and having only two suppliers would create highly restricted competitive conditions. Arkema also commented that the manufacturer has not publicly announced production capacities for the coming years and EPA has not provided reliable evidence, and none exists, that adequate volumes of HFO-1234vf are or will be available to "meet current and projected domestic auto industry demand." Global Automakers commented that it is too soon to conclude that there will be adequate supplies of alternative refrigerants to meet U.S. demand as well as other possible demands for alternative refrigerants worldwide by MY 2021.

Response: Based on EPA's understanding of refrigerant supply at the time of the proposed rule, the information received from commenters

in response to the proposed rule, and information claimed as confidential and provided during meetings, EPA remains confident that sufficient supply of alternatives will exist to transition MVAC systems in all new light-duty vehicles manufactured in the United States by MY 2021. EPA is fully aware of delays with the launch of some production facilities prior to the implementation of the European Union regulations. However, EPA notes that those facilities are now online and are producing supplies well in excess of what is needed to meet EU demand. They are not currently operating at full capacity. Moreover, Honeywell and DuPont, two producers of HFO-1234yf, provided information regarding plans to launch additional facilities, one of which will be a joint effort between Honeywell and a third chemical manufacturer, AGC.53 For these reasons, EPA does not agree with commenters that there will be an insufficient supply of alternatives by MY 2021. Further, EPA is also aware of public announcements by Arkema indicating planned production in 2017 of HFO-1234yf.<sup>54</sup>

Comment: Commenters indicated concern because available supply of HFO–1234yf will need to go to Europe for the January 1, 2017, transition before automobile manufacturers will have access to supply to transition in the United States. These commenters believe a MY 2025 or later transition date would allow sufficient time to alleviate supply concerns.

Response: EPA does not agree that the January 1, 2017, transition in the EU will limit supply in the United States. The SNAP transition date is several years after the transition in the EU will be complete and, as noted above, the manufacturers of HFO–1234yf have provided information supporting that supply will be adequate by MY 2021. EPA does acknowledge that supply in the United States would likely not be adequate by MY 2017. The main suppliers of HFO–1234yf stated as much in their comments.

Comment: Mexichem commented that the "pending re-examination proceedings involving sham patents

registered by Honeywell, continue to be a barrier to the effective development of HFO-1234yf." Arkema commented that EPA overlooks the considerable efforts that Honeywell has undertaken to maintain its exclusive control over the manufacture of HFO-1234vf. Arkema commented that "Although legal proceedings and investigations regarding Honeywell and DuPont's exclusive control of HFO-1234yf are underway at the European Commission, the Federal Trade Commission, the U.S. Patent & Trademark Office, and elsewhere, those proceedings and investigations are not yet resolved." Arkema stated that "until those investigations are resolved, Honeywell and DuPont will control the manufacture of HFO-1234yf and will impose restrictive supply conditions, all with the apparent de facto endorsement of the EPA in violation of the Sixth Principle to "not endorse products manufactured by specific companies". Arkema adds that this will slow the transition to HFO-1234yf and add to its

Response: EPA is aware that proceedings and investigations are occurring related to the patents on HFO-1234yf; however, EPA is not involved and cannot comment on these proceedings. EPA believes that based on the information available today, sufficient supply will be available of HFO-1234yf for a full transition in MY 2021 for new light-duty MVAC systems even if all manufacturers choose to use HFO–1234yf. Regarding the comment that this action is in violation of the "Sixth Principle," we disagree that EPA endorsed HFO-1234yf or the companies producing it by its inclusion on the list of acceptable substitutes for the MVAC end-use at issue in this action. HFO-1234yf is one of three acceptable lower-GWP alternatives and EPA does not believe it is appropriate to assume manufacturers will use only HFO-1234yf. In addition to HFO-1234yf, CO<sub>2</sub> and HFC-152a are listed as acceptable and the manufacturers can choose which substitute they wish to use in their product. EPA does not recommend or require the use of a specific refrigerant and does not endorse products manufactured by specific companies. At least one global motor vehicle manufacturer has announced plans to have cars with MVAC systems using CO<sub>2</sub> on the road in Europe by MY 2017; we are not aware of any reason why such models would not be introduced into the United States by MY 2021. EPA is also aware of a demonstration project planned by a major Indian motor vehicle

manufacturer considering HFC–152a and HFO–1234yf in MVAC systems using secondary loops (Andersen et al., 2015). As noted elsewhere in this final action, EPA is aware of ongoing research and development which could ultimately result in future listings of additional alternatives and notes that since the issuance of the proposal the Agency received a submission for one additional MVAC alternative.

#### (b) Interaction With EPA's LD GHG Rule

Comment: EPA received several comments related to the interaction of this rulemaking with EPA's LD GHG Standards. Commenters requesting a MY 2025 or later transition, including AAM, Global Automakers, the National **Automobile Dealers Association** (NADA), and Mexichem, commented that the later date would preserve the integrity and commitments made under the GHG program, preserve the compliance flexibilities granted to automakers and provide the same environmental benefits. Commenters stated that a MY 2025 transition allows for full compliance flexibility, in addition to credits, allotted to manufacturers in the vehicle GHG rulemakings throughout MYs 2012-2025. AAM requested that EPA "state clearly and unequivocally that EPA is committed to continuing the A/C credits through MY 2025 and beyond" and asked EPA to include this certainty in the regulatory text of the final SNAP rule and not just in the preamble.

Response: Nothing in this final rule changes the regulations establishing the availability of air conditioning refrigerant credits under the GHG standards for MY 2017–2025, found at 40 CFR 86.1865-12 and 1867-12. The stringency of the standards remains unchanged. As stated above, manufacturers may still generate and utilize credits for substitution of HFC-134a through the 2025 model year. Further, this final rule is also not in conflict with the Supplemental Notice of Intent (76 FR 48758, August 9, 2011) that described plans for EPA and NHTSA's joint proposal for model years 2017-2025, since EPA's GHG program continues to provide the level of air conditioning credits available to manufacturers as specified in that Notice. Specifically, the Supplemental Notice of Intent states that "(m)anufacturers will be able to earn credits for improvements in air conditioning. . . systems, both for efficiency improvements . . . and for leakage or alternative, lower-GWP refrigerants used (reduces [HFC] emissions)." 76 FR at 48761. These credits remain available under the light-

<sup>&</sup>lt;sup>53</sup> AGC, 2014. "AGC to Supply Honeywell with HFO–1234yf—New-generation Automobile Refrigerant," January 23, 2014. This document is accessible at: https://www.agc.com/english/news/2014/0123e.pdf.

<sup>54</sup> Arkema, 2013. "Arkema is announcing the construction of production capacities for new refrigerant fluorinated gas 1234yf," September 4, 2013. This document is accessible at: www.arkema.com/en/media/news/news-details/Arkema-is-announcing-the-construction-of-production-capacities-for-new-refrigerant-fluorinated-gas-1234yf/?back=true.

duty program at the level specified in the Supplemental Notice of Intent, and using the same demonstration mechanisms set forth in that Notice. Moreover, the supporting assessment for this rulemaking is consistent with the assumptions set forth in the 2017–2025 LD GHG Rule that automakers would switch to lower-GWP refrigerants by MY 2021. Indeed, the standards' stringency was predicated on 100% substitution beginning in MY 2021.<sup>55</sup>

We are not adding a statement to the regulatory text in the final SNAP rule. As noted in the preamble to the proposed rule, and reiterated here: "The light duty standards do provide that manufacturers can generate credits from use of alternative refrigerants with lower GWPs than that of HFC-134a through MY 2025, and the ability to generate and use those credits towards compliance with the light duty standards will not change if this action is finalized as proposed." (79 FR 46142)

# (c) Environmental Impacts

Comment: Several commenters addressed the climate impacts of the proposed HFC-134a unacceptability determination for MVAC. The vast majority of commenters on this section of the rule support a transition to climate-friendly alternatives in MVAC due to HFC-134a's high global warming potential. Several commenters supporting transition prior to MY 2021 related these impacts to the proposed timeline for the transition and we addressed those comments above (e.g., that if an earlier change of status date were adopted, there would be additional environmental benefits). Commenters requesting a transition date of MY 2025 or later commented that the environmental benefits of a delayed change of status date will be substantially the same as a MY 2021 transition because the majority of vehicles will transition by MY 2021 as a result of the LD GHG Rule. These commenters stated that any benefits of a MY 2021 or earlier transition may be averaged out against tailpipe emissions, and could result in automobile manufacturers slowing other fleet GHG reductions. DuPont commented that it is unlikely that any additional credits achieved under the LD GHG regulations from a MY 2019 transition date would be fully offset and instead there would likely be net additional CO2 reductions over those achieved by current regulations. Arkema commented that there is no significant climate risk reduction to be had from any SNAP

action on HFC–134a in the MVAC sector, and that no further control, beyond that imposed by the LD GHG Rule, is necessary.

Response: EPA anticipates that if a change of status date earlier than MY 2021 were shown to be feasible and thus were adopted, additional environmental benefits would be gained beyond those accounted for under EPA's analysis to support the LD GHG Rule.<sup>56</sup> In EPA's analysis of the environmental benefits associated with the proposed and final change of status rule, EPA assumed no environmental benefits from domestic transition of MVAC systems in lightduty vehicles given that the environmental benefits resulting from a full transition by MY 2021 were accounted for in the LD GHG Rule. The LD GHG Rule anticipated that transition for MVAC systems manufactured for use in the United States, while continuing to provide flexibility to manufacturers until MY 2025. This rule, however, ensures a complete transition away from HFC-134a by MY 2021 to a refrigerant that reduces the overall risks to human health and the environment for all MVAC systems manufactured in the United States, including those exported to other countries,<sup>57</sup> and those imported into the United States. The benefits analysis includes these benefits. Also, the analysis was updated to reflect the potential impact of the narrowed use limits in this final rule that allow continued use of HFC-134a for vehicles exported to countries with inadequate infrastructure to support safer alternatives. For additional information on environmental benefits analysis conducted for this rule, see the supporting document "Climate Benefits of the SNAP Program Status Change Rule" (EPA, 2014; EPA, 2015b).

Comment: Arkema commented that the NPRM deprives U.S. plants of existing global business in HFC–134a without yielding any environmental benefit. Arkema also noted that EPA said, as part of its regulations for HCFCs, that production of HCFC–22 for export from the U.S. might displace production in other countries that do not control their emissions as stringently as U.S. chemical producers. Arkema stated, "if U.S. production of HCFCs reduces overall environmental risks, then so does U.S. production of HFC–134a, and EPA should not be using

the risk-based SNAP program to restrict auto exports."

Response: This rule does not directly regulate production of HFC-134a, unlike the rulemaking on the phaseout of HCFCs that Arkema cited; rather, we are regulating use of HFC-134a as a substitute in specific uses. Further, we disagree with Arkema's assertion that U.S. production of HFC-134a would potentially reduce overall environmental risks if U.S. production of HCFCs reduces environmental risks. EPA's HCFC allocation rule specifically mentioned that HCFC-22 production (and not production of HCFCs in general) results in byproduct emissions of HFC-23, a gas with a very high GWP of 14,800. The commenter has not provided any information indicating that emissions from production of HFC-134a, with a GWP of 1,430, or its byproducts would have a similar high environmental impact. We disagree with the commenter's assumptions as well as the conclusion that the SNAP program should not regulate exports of vehicles.

Comment: AAM stated that the MVAC-related climate benefits of this rulemaking have been incorrectly calculated and that "the environmental benefits of a MY 2025 change of listing status date are substantially the same as in MY 2021 date." AAM also commented that the cessation of exports of vehicles containing HFC-134a to EU countries should not be included in the benefits calculation because the EU already prohibits the use of HFC-134a and that subtracting exports to EU countries and to Canada would reduce the climate benefit due to exports by half to 1 MMTCO2eq.

Response: EPA directs commenters to the benefits analysis associated with the final rule and in particular to the anticipated long term change in the trajectory for high-GWP HFCs and alternatives. The benefits analysis is available in the docket and reflects the final decisions in this action. It has been updated since the issuance of the NPRM to reflect changes between the NPRM and the final rule. The benefits analysis for the final rule does not include vehicles sold into the EU or Canada, given the EU's existing F-gas regulations and MAC Directive, and for Canada, the relationship between their market and

# (d) Cost Impacts of Rule

Comment: EPA received several comments concerning the cost impact of this rulemaking for the MVAC end-use. AAM, Global Automakers, and Mexichem commented that delaying transition to MY 2025 or later would avoid costs and engineering burdens on

 $<sup>^{55}</sup>$  See id. at 62,779; see also id. at 62778 and 62805

<sup>&</sup>lt;sup>56</sup> See Chapter 7 of the Regulatory Impact Analysis: Final Rulemaking for 2017–2025 Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards, EPA—420–R–12–016, August 2012.

<sup>&</sup>lt;sup>57</sup> Except those vehicles subject to the narrowed

manufacturers resulting from making adjustments to their refrigerant changeover plans for both vehicles and manufacturing plants. NRDC and IGSD commented that a transition date of MY 2017 would align the U.S. and EU markets and erase these competitive disadvantages with minimal impact to industry. The Automotive Refrigeration Products Institute (ARPI) and Auto Care Association commented that a change from HFC-134a to lower-GWP refrigerants should not cause any substantial economic hardship to car owners. Additional comments relating to EPA's economic analysis are included in section VII.B of the preamble, "Cost and economic impacts of proposed status changes."

Response: EPA understands that there are challenges associated with transitioning refrigerants, including costs to manufacturers in redesigning equipment and making changes to manufacturing facilities. However, as explained in more detail in the response to comments later in this preamble, under the SNAP criteria for review in 40 CFR 82.180(a)(7), consideration of cost is limited to cost of the substitute under review, and that consideration does not include the cost of transition when a substitute is found unacceptable. Moreover, we note that during model redesigns, many other engineering changes are being made and that changing the MVAC system during a planned redesign cycle could reduce costs when compared to MVAC system changes mid-redesign cycle. We anticipate that a change of status in MY 2021 will allow manufacturers to make changes to the MVAC systems for most vehicle models as part of the model redesign process.

Comment: A few commenters noted the high price of HFO–1234yf relative to HFC–134a. One commenter, referring to the NPRM, stated that EPA continues to believe that HFO–1234yf is unlikely to ever be as inexpensive as HFC–134a is currently. Commenters stated that the high price of HFO–1234yf is likely to slow the transition away from HFC–134a in the United States.

Response: As explained in more detail in the response to comments later in this preamble, under the SNAP criteria for review in 40 CFR 82.180(a)(7), the only cost information that EPA considers as part of its SNAP review is the cost of the substitute under review. As part of EPA's cost analysis conducted in support of this rulemaking, the potential costs to manufacturers were estimated based on per-system costs of alternative systems, as identified in EPA's report on Global Mitigation of Non-CO<sub>2</sub> Greenhouse

Gases: 2010-2030 (EPA, 2013a), and converted to 2013 dollars. The incremental per-system cost of an alternative MVAC system compared to an HFC-134a system is estimated to be about \$62/unit. EPA previously analyzed these costs in documents supporting the LD GHG Rule and in that analysis accounted for the cost of 100% of domestic vehicles to transition to use of HFO-1234yf by MY 2021. These incremental costs are less than 1% relative to the total direct manufacturing cost for a light-duty vehicle.<sup>58</sup> EPA does not believe an incremental cost of less than 1% of the total direct manufacturing cost will slow the transition away from HFC-134a. EPA understands that often new alternatives have higher initial costs, but this is not always true. In addition, over time the cost of the alternative often drops as demand and supply increase.

Comment: Global Automakers and AAM commented that if EPA includes exports in this regulation, EPA would be placing U.S.-based manufacturers of export vehicles at a competitive disadvantage compared to automakers producing vehicles outside of the United States. Global Automakers stated in their comment that "this rulemaking will unnecessarily cause substantial economic harm to the U.S. economy, U.S. jobs, and balance of payments if exports are included in the regulatory provisions." Arkema, Mexichem, and BMW also commented on the potential economic impacts of regulating exports.

Response: An inability to export vehicles manufactured with HFC-134a could be a competitive disadvantage in any countries where vehicles manufactured with other alternatives cannot be supported. However, as discussed above, the additional cost of a vehicle manufactured using an alternative (e.g., HFO-1234vf) is anticipated to be approximately \$62 more per vehicle; this is not sufficient to create a competitive disadvantage in countries where both HFC-134a and other alternatives are supported. Further, EPA is providing a narrowed use limit in this final action that would allow vehicles destined for export to a country with insufficient infrastructure to be manufactured with HFC-134a through MY 2025. Thus, U.S. manufacturers should not experience a competitive disadvantage.

# (e) Servicing and Retrofits

Comment: EPA received comments related to the continued servicing of MVAC systems manufactured to use HFC–134a. Two commenters support the continued acceptability of HFC-134a for servicing, and one commenter requests assurance that continued servicing will be permitted. ARPI and the Auto Care Association, representing the automotive aftermarket industry, jointly commented that they support the change of status of HFC-134a in MVAC provided that systems using replacement refrigerants are available at the time at a reasonable price and that the "phase out" does not adversely affect the use of HFC-134a in the millions of vehicles which will then still have MVAC systems designed for that refrigerant.

Response: EPA did not propose and is not finalizing a change of status for HFC–134a used for servicing MVAC systems designed to use HFC–134a. Thus, vehicles manufactured to use HFC–134a may, consistent with this rule, continue to be serviced with HFC–134a.

Comment: EPA received a comment requesting clarification on the ability to retrofit or service an HFO–1234yf system with HFC–134a.

Response: As discussed elsewhere in the preamble, the SNAP regulations include use conditions and other requirements that limit the ability to service an MVAC system designed to use an alternative with a refrigerant other than the one the system was designed to use. See section V.B.3 for a detailed description.

Also, as discussed in more detail in section V.B.3, for vehicles for which the manufacturer counts air conditioning credits toward its LD GHG compliance, the MVAC systems (or elements of those systems) are considered emission-related components as defined in 40 CFR 86.1803. This designation includes provisions for emission-related warranty, requirements that they operate properly for the specified useful life, and tampering restrictions.

# (f) Refrigerant Blends for Retrofits of MVAC Systems

Comment: Two commenters requested that EPA also list the refrigerant blends as unacceptable for use in retrofits in the final rule as well as in new equipment. SAE Interior Climate Control Committee (SAE ICCC), the leading standards writing body in the United States for MVAC, commented that they support the extension of the unacceptability finding to retrofits because they have never written any

<sup>&</sup>lt;sup>58</sup> Environmental Protection Agency (EPA) and National Highway Traffic Safety Administration (NHTSA). 2012. Joint Technical Support Document: Final Rulemaking for 2017–2025 Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards. August 2012. Available online at: http://www.epa.gov/otaq/ climate/documents/420r12901.pdf.

standards for these refrigerants. The other commenter, DuPont, recommended that because the refrigerants are not currently in use and it would be undesirable to have them used, EPA should also change the SNAP status for the blend refrigerants to unacceptable for retrofit (in addition to new) MVAC uses.

Response: EPA has not undertaken the full analysis necessary to determine whether to list these refrigerant blends as unacceptable for retrofits. Accordingly, EPA did not propose to find the refrigerant blends unacceptable for retrofits. Additional information, as well as an opportunity for public comment, would be necessary before we would be able to potentially find the refrigerant blends unacceptable for use in retrofits (e.g., information on the extent of use of the refrigerant blends). EPA appreciates the comments submitted on this topic and will take them into consideration when preparing additional status change rules.

#### (g) Use Conditions for HFC-134a

Comment: Arkema commented that it is "arbitrary and capricious" for EPA to find acceptable substances that could compete with HFC-134a in MVAC only because those other substances are subject to use conditions, and then to find HFC-134a unacceptable based on comparisons to those other substances without considering any comparable use restriction on HFC-134a. The commenter referred to a discussion in the proposed rule concerning establishing charge limits through use conditions for a number of high GWP refrigerant blends for use in supermarket systems and condensing units as an example.

Response: EPA has not proposed additional use conditions for HFC–134a comparable to those for HFO-1234yf, HFC-152a, and CO<sub>2</sub> because the ways of addressing risks for these substitutes are not comparable. The use conditions unique to HFO-1234yf and HFC-152a address flammability risks through engineering strategies that will keep refrigerant concentrations below the lower flammability limit in each vehicle and by requiring labels providing information on the flammability risk. The use conditions unique to CO<sub>2</sub> address toxicity and consumer exposure risks through requiring engineering strategies that will keep refrigerant concentrations at safe levels in the passenger compartment of the vehicle. In contrast, the environmental risks from HFC-134a are due to the collective global impact of refrigerant emissions released over time from the entire automotive industry.

In past cases where the SNAP program has regulated other substitutes that posed high environmental risk due to collective global emissions, we have taken three different approaches. One approach has been to restrict the substitute to a niche use through a narrowed use limit, where it was particularly difficult to find any feasible substitute and the niche use was unlikely to result in significant total emissions (e.g., narrowed use limit on high-GWP fire suppressant SF<sub>6</sub> for use only as a discharge agent in military applications and in civilian aircraft at appendix B to 40 CFR part 82, subpart G). A similar approach has been to restrict the substitute through a narrowed use limit to use only "where other alternatives are not technically feasible due to performance or safety requirements" (e.g., narrowed use limits on perfluorocarbon solvents for precision cleaning and C<sub>6</sub>F<sub>14</sub> as a total flooding agent for fire suppression at appendix A to 40 CFR part 82, subpart G). The third approach EPA has used to address environmental risks from global emissions of a substitute, and the only approach we have taken to date for such a substitute that is already widespread in industry, is to find the substitute unacceptable (e.g., HCFC-141b in solvent cleaning at appendix A to 40 CFR part 82, subpart G and HCFC-141b in foam blowing at appendix M to 40 CFR part 82, subpart G). MVAC is not a niche use, and there are clearly other technically feasible substitutes that will be available by the status change date specified in this final rule for use in vehicles that will be sold domestically, so it is not reasonable to provide a narrowed use limit for HFC-134abeyond that established in this final rule for export to nations with insufficient infrastructure for other alternatives.

Concerning Arkema's reference to a discussion on use conditions for charge size limits, we note that in the proposed rule we also stated, "However, given the high GWP of these refrigerants compared to other refrigerants that are available in these end-uses, we do not believe that use with a small charge size adequately addresses the greater risk they pose." This is even more so in MVAC than in commercial refrigeration products, due to the more widespread use of MVAC in hundreds of millions of vehicles and the greater difference in GWP between the unacceptable substitute and other, lower-GWP alternative, compared to supermarket systems and remote condensing units.

# (h) Flexibility for Exports

Comment: NRDC, IGSD, and DuPont suggested that if EPA finalizes MY 2017

or MY 2019, respectively, EPA could consider narrowed use limits to address any sub-sectors that have problems meeting a transition date earlier than MY 2021, if, for example, the Agency believed there was a basis to claims of country-specific performance barriers (e.g., due to high ambient temperatures) or lack of infrastructure for safer alternatives.

Response: As discussed further in this section, EPA has finalized a narrowed use limit for certain vehicles to be exported to countries that have not yet developed sufficient infrastructure for using safer alternatives. EPA has received no documentation supporting a narrowed use limit related to ambient temperature conditions, and therefore, has not included such a narrowed use limit in this final action.

Comment: EPA received comments from several commenters related to the servicing infrastructure for lower-GWP alternatives outside the United States. Some details are provided below and the remaining details can be found in the Response to Comments document. Arkema, Mexichem, BMW, AAM, and Global Automakers raised concerns including whether destinations for exported vehicles will have sufficient service sector support and refrigerant distribution networks for HFO-1234yf; and the ability to conform to SNAP use conditions, given the large proportion of automobiles manufactured in the U.S. for export (up to one-fourth). Commenters question whether the alternatives are truly "available" for use in export markets if there is a lack of service sector support and comment that this regulation could lead to manufacturers having to limit export production at U.S. assembly plants. Commenters are also concerned about the time needed to overcome regulatory and legislative barriers. AAM suggested that EPA designate certain export markets that can still receive U.S. exports of HFC-134a vehicles, which they believe currently should be all export markets except Canada and Europe.

In contrast, DuPont and Honeywell, manufacturers of HFO–1234yf, asserted that service supply follows demand and the equipment for low GWP refrigerant service is readily available. These commenters stated that dealers and service shops can be expected to acquire the necessary equipment and materials to serve the market demand and that it is the responsibility of the vehicle manufacturer to ensure that their authorized dealers in those countries are able to provide all the necessary service to these exported cars under warranty. Honeywell and DuPont both stated that

they have already developed an extensive network of distributors that are capable of supplying HFO–1234yf globally. DuPont stated that based on demand from the motor vehicle aftermarket, they have distribution covering more than 40 countries, 11 more than the combined EU member states and the United States, and including Saudi Arabia, Turkey, Israel and the United Arab Emirates.

Response: EPA is aware that many countries, in addition to Canada and those in the EU, already have servicing infrastructure in place, and anticipates that the number will grow by MY 2021. However, EPA also recognizes that there may be some markets where additional time may be needed to ensure servicing infrastructure is available. EPA is providing a narrowed use limit for HFC–134a in new MVAC systems destined for use in countries that do not have infrastructure in place for servicing with other acceptable refrigerants. This narrowed use limit will remain in place through MY 2025. The remaining information in this response explains why EPA believes it is not necessary to have a narrowed use limit in place indefinitely. EPA is particularly encouraged to learn that there is currently distribution for HFO-1234yf in 40 countries, 11 more than the combined EU member states and the United States and, that these countries include Saudi Arabia, Turkey, Israel and the United Arab Emirates, which indicates that infrastructure is already being put in place in a significant number of countries.

EPA does not agree that every country in the world would need as much time as was needed in North America and Europe to resolve barriers to transition. Many countries look to the SNAP program and the EU's REACH program as a source of information to inform their domestic programs and, thus transition for those countries should proceed more quickly. EPA notes the widespread use of flammable refrigerants for various end-uses in other countries (more so than in the United States) as well as the inclusion of such refrigerants for projects considered by the Executive Committee of the Montreal Protocol's Multilateral Fund. We anticipate that many countries that do not have adequate infrastructure in place in 2015 will have it in place in time to service MY 2021 vehicles.

In many cases international agencies, such as the United Nations Environment Programme (UNEP), have been working with developing countries to facilitate changes in domestic regulations to allow for the use of lower-GWP solutions. This has been particularly

true since 2007 when the Parties to the Montreal Protocol adopted a more aggressive phaseout schedule for HCFCs, for end-uses using HCFCs such as stand-alone commercial refrigeration appliances. Thus there are systems in place for communicating information on new refrigerants and for sharing experience. Further, the experiences of the United States and Europe are being shared widely. We have provided information to the Montreal Protocol's Secretariat and to UNEP. We already are also seeing information shared through a range of mechanisms by the Secretariat and UNEP as well as included in reports of the Montreal Protocol's Technical and Economic Assessment Panel (TEAP), SAE, and other bodies.

In addition, EPA notes that the G-7 leaders committed in June 2014 to promote the rapid deployment of climate-friendly and safe alternatives to HFCs in motor vehicle air-conditioning and to promote public procurement of climate-friendly HFC alternatives. EPA notes that many countries already are committed to take action to promote public procurement of climate-friendly lower-GWP alternatives whenever feasible and would likely consider MVAC as a potentially feasible end-use. For the reasons above, we believe that sufficient progress is being made and will continue to be made such that the narrowed use limit need not apply beyond MY 2025.

*Comment:* Global Automakers commented that it is imperative to have trained technicians and shops equipped with the necessary equipment to service and repair MVAC systems using flammable refrigerants, and special equipment is needed to recover, recycle, and re-charge flammable refrigerants before vehicles using such refrigerants can be marketed in a specific country. AAM commented that on average, every vehicle gets completely recharged with new refrigerant at least once during its lifetime, and therefore, the unique need for such widespread service support for MVAC differentiates this situation from past SNAP considerations of export markets for other appliances.

Response: EPA agrees with the value of providing information and training to technicians. In the United States, we are currently working with technician certification programs to include information on HFC–152a, R–744, and HFO–1234yf. EPA agrees with commenters that there is value in technician training and education on a global basis. International agencies such as UNEP could potentially be a source of such training in developing countries. EPA does not agree that it is necessary

to ensure such training is in place in all markets worldwide in order to fully accommodate U.S. exports with the new refrigerants. EPA has already developed information on the newer alternative refrigerants acceptable in the United States that is available on our Web site and could be a resource for others. In addition, the use conditions requiring labeling and unique fittings for refrigerants for MVAC for service equipment and vehicle service ports serves as a means for informing technicians as to what refrigerant is being used.

EPA understands that the commenters are suggesting that there still may be markets that do not have infrastructure in place by MY 2025. Based on the speed of transition that we are seeing, EPA does not agree. However, the Agency could consider proposing a change in the future if needed.

C. Retail Food Refrigeration and Vending Machines

#### 1. Background

(a) Overview of SNAP End-Uses, End-Use Categories and Commonly-Used Refrigerants

EPA refers readers to section V.C.1 of the preamble to the proposed rule for a detailed discussion of the end-uses within the refrigeration sector covered by this rule as well as information on some of the refrigerants used within those end-uses.

In the proposed rule, EPA proposed to change the listing for certain refrigerants for two end-uses within the "commercial refrigeration" sectorretail food refrigeration and vending machines. Retail food refrigeration, as affected by today's rule, is composed of three main categories of equipment: Stand-alone equipment; remote condensing units; and supermarket systems. Stand-alone equipment consists of refrigerators, freezers, and reach-in coolers (either open or with doors) where all refrigeration components are integrated and, for the smallest types, the refrigeration circuit is entirely brazed or welded. These systems are termed "stand-alone" within the SNAP program because they are fully charged with refrigerant at the factory and typically require only an electricity supply to begin operation.

Condensing units, called remote condensing units in this final action as discussed below, exhibit refrigerating capacities that typically range from 1 kW to 20 kW (0.3 to 5.7 refrigeration tons) and are composed of one (and sometimes two) compressor(s), one condenser, and one receiver assembled into a single unit, which is normally

located external to the sales area. The modifier "remote" indicates that the condenser (and often other parts of the system) are not located in the space or area cooled by the evaporator but are instead located outside the room, typically ejecting heat to the outdoor ambient environment. Remote condensing units are commonly installed in convenience stores and specialty shops such as bakeries and butcher shops, as well as in supermarkets, restaurants and other locations where food is stored, served or sold.

Typical supermarket systems are known as multiplex or centralized systems. They operate with racks of compressors installed in a machinery room. Two main design classifications are used: Direct and indirect systems. At least 70% of supermarkets in the United States use centralized direct expansion (DX) systems to cool their display cases. 59 In these systems, the refrigerant circulates from the machinery room to the sales area, where it evaporates in display-case heat exchangers, and then returns in vapor phase to the suction headers of the compressor racks. Another direct supermarket design, often referred to as a distributed refrigeration system, uses an array of separate compressor racks located near the display cases rather than having a central compressor rack system. Indirect supermarket designs include secondary loop systems and cascade refrigeration. Indirect systems use a chiller or other refrigeration system to cool a secondary fluid that is then circulated throughout the store to the cases.

Refrigerant choices depend on the refrigerant charge (i.e., the amount of refrigerant a system is designed to contain under normal operating conditions), the product temperature required, energy efficiency, system performance, ambient temperatures, operating conditions, potential impact on community safety, potential risk to personal safety, cost, and minimization of direct and indirect environmental impacts, among other things. In addition, federal or local regulations may also affect refrigerant choice. For instance, regulations from the OSHA may restrict or place requirements on the use of some refrigerants, such as ammonia (R-717). Building codes from local and State agencies may also incorporate limits on the amount of particular refrigerants used. There are and will continue to be a number of factors that retailers must consider when selecting the refrigerant and

operating system design. While a number of approaches exist, there is no uniformly accepted holistic analysis of the multiple factors listed above. EPA recognizes that there must be a range of options, and that the decision as to which option to select must remain with the owner and operator of the system.

# (b) Terms and Coverage

During a meeting with EPA just prior to publication of the proposed rule, an industry trade organization representing manufacturers of refrigeration equipment, Air-Conditioning, Heating, and Refrigeration Institute (AHRI), raised concerns that in some situations the definitions and categories used in the SNAP program differ from those used by the U.S. Department of Energy (DOE) and/or the industry and they submitted a document identifying those definitions and categories (see EPA Meeting on Commercial Refrigeration Equipment-June 10, 2014 under Docket ID# EPA-HQ-OAR-2014-0198-0005). They indicated that the term "commercial refrigeration" is often first divided by the type and location of the condensing unit, using two broad terms. "Remote condensing" is used to indicate systems where the condensing unit and compressors are located remotely from where food is stored or displayed and instead the refrigerant or secondary-fluid is piped to the cases or rooms where the food is located. "Selfcontained" is used to indicate that the condensing unit (along with the compressor and evaporator) is integrated into the case in which the food is stored and displayed. These units are generally initially charged by the case manufacturer at the manufacturing plant.

EPA notes that the term "selfcontained" is synonymous with the SNAP end-use category "stand-alone" and we are retaining use of the term stand-alone for this rulemaking action. The term "remote condensing" applies to the SNAP end-use categories of "supermarket systems" and "condensing units." For the latter enduse category, in this final rule we are revising the term "condensing units" to be "remote condensing units." EPA draws a distinction between "supermarket systems" and "remote condensing units" based on the number of compressors in the remote condensing system. Supermarket systems generally have more than two compressors arranged in a "rack" whereas remote condensing units typically have only one or two compressors linked to a single condenser. For purposes of this rule, we are keeping these two categories separate.

The AHRI document (Docket ID# EPA-HQ-OAR-2014-0198-0005) also attempts to draw an additional distinction regarding commercial walkin coolers and freezers. We note that we do not treat such units separate from the categories described above. Rather such units would fall within the end-use category "supermarket system" if the refrigerant is supplied on the same multi-compressor circuit used to cool food elsewhere in the store or within the end-use category "remote condensing unit" if only a one- or two-compressor system is used (generally dedicated to just the individual walk-in cooler or freezer).

AHRI further notes that both supermarket systems and remote condensing units can be connected to various types of display cases designed to maintain products at various temperatures, often subdivided as "medium-temperature"—roughly between 32 °F (0 °C) and 41 °F (5 °C)and "low-temperature"—roughly between  $-40\,^{\circ}\text{F}$  ( $-40\,^{\circ}\text{C}$ ) and  $32\,^{\circ}\text{F}$ (0 °C). EPA notes that within the SNAP end-uses and categories described above, no distinction is currently made based on application temperature (medium or low) and so the decisions finalized in today's rule apply to all equipment fitting within the supermarket and remote condensing units end-use categories as described; however, based on comments received, within the stand-alone equipment enduse category a distinction is made between equipment designed for "low" temperatures and other equipment.

During the comment period on the proposed rule, we received additional questions and comments about whether certain types of equipment were included in the end-uses addressed in this action. We are clarifying here that specific types of equipment used in the food industry do not fall within the enduses and end-use categories affected by this rule: Blast chillers, ice making machines not connected to a supermarket system, very low temperature refrigeration, and certain food and beverage dispensing systems

food and beverage dispensing systems. A "blast chiller" or "blast freezer" is a type of equipment in which cold air is supplied and circulated rapidly to a food product, generally to quickly cool or freeze a product before damage or spoilage can occur. Such units are typically used in industrial settings (e.g., at a factory or on a large fishcatching vessel) and fall under the SNAP end-use "Industrial Process Refrigeration" and hence are not subject to this rule.

 $<sup>^{59}</sup>$  www2.epa.gov/greenchill/advanced-refrigeration.

"Ice makers" are machines designed for the sole purpose of producing ice, in various sizes and shapes, and with different retrieval mechanisms (e.g., dispensers or self-retrieval from bins). Under SNAP, "commercial ice machines" are identified as a separate end-use not part of the retail food refrigeration end-use (e.g., not a "standalone" unit). See e.g., 59 FR 13070 (March 18, 1994) where EPA clearly designated "commercial ice machines" as a separate end-use than "retail food refrigeration." Thus, both self-contained ice makers, as well as ice-making units solely connected via piping to a dedicated remote condenser, do not fall under the retail food refrigeration enduse and hence are not subject to this rule. In contrast, ice-making units that are connected to a supermarket system are subject to this rule. For instance, if a supermarket rack system supplies refrigerant to a unit to make ice, such as for use in meat and seafood storage, display and sales, and that refrigerant and compressor rack are part of a larger circuit that also provides cooling for other products in the store, the entire system would be classified as a "supermarket system" and hence would be subject to today's rule. EPA would like to clarify that since remote condensing ice makers designed solely to be connected to a supermarket remote rack are not sold or manufactured with a condensing unit, they do not meet the definition of automatic commercial ice maker used by DOE in the automatic commercial ice maker energy conservation standards.

Several commenters, including Master Bilt Products and Thermo Fisher, identified products they manufacture to reach temperatures of  $-50^{\circ}F$  ( $-46^{\circ}C$ ) or even lower. These products fit under the end-use "very low temperature refrigeration" and hence are not covered by this rule. EPA also notes that it recently found R–170 (ethane) as acceptable, subject to use conditions, in the very low temperature refrigeration end-use. (April 10, 2015; 80 FR 19453)

Other commenters, such as Emerson, HC Duke/Electro-Freeze, and United Technologies, mentioned equipment designed to make or process cold food and beverages that are dispensed via a nozzle, including soft-serve ice cream machines, "slushy" iced beverage dispensers, and soft-drink dispensers. Such equipment can be self-contained or can be connected via piping to a dedicated condensing unit located elsewhere. EPA does not consider this equipment to fall under either the "stand-alone" or "remote condensing unit" categories of retail food refrigeration. While our definition of

retail food refrigeration includes "cold storage cases designed to chill food for commercial sale," these units generally do more than just store food or beverages. For instance, United Technologies states such equipment "transform[s] a liquid product into a frozen beverage or confection with the incorporation of air to provide uniformity and specific customer requirements. These products are transformed and manufactured within the equipment, held in a frozen state and ultimately dispensed into a serving vessel that is provided to an end customer." Hence, these types of products are in a category separate from the three "retail food refrigeration" enduse categories addressed in today's rule.

We also received several comments and questions regarding energy conservation standards established by DOE and how the equipment subject to this rule is also subject to the DOE standards. While EPA is not making any decisions on the applicability of the DOE standards to specific equipment, we see that at least three such standards and perhaps more apply to types of equipment that are also subject to this rule. These three standards are titled **Energy Conservation Standards for** Commercial Refrigeration Equipment (79 FR 17725; March 28, 2014), Energy Conservation Standards for Walk-In Coolers and Freezers (79 FR 32049; June 3, 2014) and Energy Conservation Standards for Refrigerated Bottled or Canned Beverage Vending Machines (74 FR 44914; August 31, 2009). These are referred to in this rule using shortened names or a generic name such as "DOE Standards.'

The Commercial Refrigeration Equipment Standards have an effective date of May 27, 2014 and a compliance date of March 27, 2017. The Walk-In Coolers and Freezers Standards have an effective date of August 4, 2014 and a compliance date of June 5, 2017. The Beverage Vending Machines Standards have effective dates of October 30, 2009 and August 31, 2011 and a compliance date of August 31, 2012. DOE posted a notice of a public meeting and availability of the Framework document for an expected proposed rule to amend the standards for refrigerated bottled or canned beverage vending machines (78 FR 33262; June 4, 2013). Material in the docket for that action indicate DOE's plans for a final rule with a compliance date three years later (see EERE-2013-BT-STD-0022).

EPA's review indicates that equipment designated in the Commercial Refrigeration Equipment Standards may fall under the supermarket systems, remote

condensing units, and stand-alone equipment end-use categories. Specifically, equipment classes designated in the DOE Standard as XXXX.RC.T, where XXXX is the equipment class, RC specifies a remote condensing operating mode code, and T indicates a rating temperature (e.g., M and L for medium and low temperature, respectively), may fall under either the supermarket system or remote condensing unit end-use category, depending on how that equipment is applied. In addition, equipment classes designated as XXXX.SC.T, where SC specifies a self-contained operating mode code, may fall under the standalone equipment end-use category.

EPA's review indicates that equipment designated in the Walk-In Cooler and Freezers Standards may fall under the supermarket systems, remote condensing units, and stand-alone equipment end-use categories. Specifically, equipment within the class descriptor Multiplex Condensing (either Medium or Low Temperature) may fall under the supermarket systems end-use category, i.e., if such a walk-in cooler or freezer utilizes refrigerant from a larger, multi-compressor (rack) system. In addition, equipment within the class descriptor Dedicated System, Outdoor System (regardless of temperature and capacity) may fall under the remote condensing units end-use category, i.e., if connected to a remote condensing unit and not integrated into a larger, multi-compressor (rack) system. Furthermore, equipment falling in the class descriptor Dedicated System, Indoor System (regardless of temperature and capacity) may fall in the stand-alone equipment end-use category, i.e., if the equipment is manufactured and fully charged with refrigerant at the factory.

EPA's review indicates that equipment covered by the Beverage Vending Machine Standards (including Class A, Class B and Combination vending machines) falls under the vending machines end-use.

In all cases, the DOE Standards apply to new equipment, not retrofitted equipment. Also, any foam used in such systems or components that are also covered (e.g. various panels and doors within the Walk-In Coolers and Freezers Standard), may fall under the rigid PU commercial refrigeration and sandwich panel end-use and be affected by the changes of status discussed in section V.D below.

(c) The Terms "New" and "Retrofit" and How They Apply to Servicing

Several commenters, including the Food Marketing Institute (FMI),

Supermarket Company ABC, and Hussmann sought clarification of the terms "new" and "retrofit" and how these terms might affect store remodels and the use of cases or other equipment that in the future are added to or replaced for existing cases or equipment.

For the refrigeration and airconditioning sector, the SNAP program has, since the inception of the program, made a distinction between new equipment and retrofitted equipment. In some cases, a particular refrigerant is acceptable or acceptable subject to use conditions only in new equipment, not in retrofits. In other cases, a particular refrigerant is only acceptable in retrofits, not new equipment. In the NPRM, EPA evaluated whether to change the status of refrigerant substitutes for retrofits separate from its evaluation of whether to change the status of refrigerant substitutes for new equipment in each of the four end-uses and categoriessupermarket systems, remote condensing units, stand-alone equipment, and vending machines addressed. Since the inception of the SNAP program, EPA has made separate determinations for refrigerants used in "new" equipment and as a "retrofit" to existing equipment. We are likewise today making separate decisions for new and retrofit equipment within the retail food refrigeration and vending machines end-uses.

EPA uses the term "retrofit" to indicate the use of a refrigerant in an appliance (such as a supermarket system) that was designed for and originally operated using a different refrigerant 60 and does not use the term to apply to upgrades to existing equipment where the refrigerant is not changed. For instance, we drew this distinction when we found R-290 acceptable for use in retail food refrigerators and freezers (stand-alone units) subject to use conditions (76 FR 78832; December 20, 2011) stating "none of these substitutes may be used as a conversion or 'retrofit' refrigerant for existing equipment designed for other refrigerants" (40 CFR part 82, subpart G, appendix R). Some alternative refrigerant providers

describe their retrofit products as "dropins" but EPA does not use that term interchangeably with retrofit (see 79 FR 64270). We recognize that some changes typically would be required for equipment to use a refrigerant other than the one for which it was designed. In many cases, lubricants need to be changed (for instance, changing from a mineral oil to a polyolester lubricant when retrofitting from a CFC to an HFC). Due to different performance characteristics, other changes may need to occur when retrofitting, such as adjustments to or replacement of thermostatic expansion valves (TXVs) and filter-driers. In addition, gaskets and other materials may need to be replaced due to different compatibility properties of the different refrigerants. Such changes could occur as part of maintenance as well as during a retrofit.

In addition to drawing a distinction between new and retrofit for the SNAP program, EPA also included a distinction between new and existing equipment in its regulations implementing the HCFC phaseout and use restrictions in section 605 of the CAA. As of January 1, 2010, use of HFC-22 and HFC-142b was largely restricted to use as a refrigerant in equipment manufactured before that date (40 CFR 82.15(g)(2); 74 FR 66412). Similarly, as of January 1, 2015, use of other HCFCs not previously controlled was largely restricted to use as a refrigerant in equipment manufactured before January 1, 2020 (40 CFR 82.15(g)(4); 74 FR 66412). In that context, EPA defined "manufactured," for an appliance, as "the date upon which the appliance's refrigerant circuit is complete, the appliance can function, the appliance holds a full refrigerant charge, and the appliance is ready for use for its intended purposes" (40 CFR 82.3, 82.302). We provided further explanations and example scenarios of how the HCFC phaseout and use restrictions apply to supermarkets in the fact sheet Supermarket Industry Q & Aon R-22 Use (www.epa.gov/ozone/title6/ phaseout/Supermarket Q&A for R-22.html).

Under today's rule, existing systems may continue to be serviced and

maintained for the useful life of that equipment using the original refrigerant, whereas new systems (including new supermarket systems) manufactured after the change of status date will not be allowed to use refrigerants for which the status has changed to unacceptable. Consistent with the definition in subparts A and I of part 82, quoted above, EPA will consider a system to be new for purposes of these SNAP determinations as of the date upon which the refrigerant circuit is complete, the system can function, the system holds a full refrigerant charge, and the system is ready for use for its intended purposes. As explained in the fact sheet referenced above, a supermarket may undergo an expansion and continue to use the existing refrigerant "if there is sufficient cooling capacity within the system to support the expansion" as EPA would consider that in such a situation "the store is not changing the intended purpose of the system." As pointed out by FMI, the replacement of existing display cases with ones that operate at a higher evaporator temperature, but still provide the same purpose of maintaining products at required temperatures, is one way in which a system may be remodeled without changing the intended purpose of the system. On the other hand, if a supermarket remodel or expansion changes the intended purpose of the original equipment, for instance by adding additional cases, compressors, and refrigerant that were not supported by the original compressor system, EPA would consider the expanded system a "new" system. In that situation, a supermarket would not be allowed to use a refrigerant that was listed as unacceptable as of the date that new system was expanded or remodeled, even if the system had been using that refrigerant before the expansion or remodel.

2. What is EPA finalizing for retail food refrigeration (supermarket systems)?

The change of status determinations for retail food refrigeration (supermarket systems) are summarized in the following table:

TABLE 4—CHANGE OF STATUS DECISIONS FOR RETAIL FOOD REFRIGERATION (SUPERMARKETS SYSTEMS)

End-use	Substitutes	Decision
Retail food refrigeration (supermarket systems) (new).	HFC-227ea, R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, R-507A.	Unacceptable as of January 1, 2017.

<sup>&</sup>lt;sup>60</sup> A chemical or mixture that is not the same as that used before the retrofit, typically denoted by different "R" numbers under ASHRAE Standard 34.

TABLE 4—CHANGE OF STATUS DECISIONS FOR RETAIL FOOD REFRIGERATION (SUPERMARKETS SYSTEMS)—Continued

End-use	Substitutes	Decision
Retail food refrigeration (supermarket systems) (retrofit).	R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, R-507A.	Unacceptable as of July 20, 2016.

# (a) New Supermarket Systems

For new supermarket systems, EPA had proposed to change the status, as of January 1, 2016, for nine HFC blends and HFC-227ea to unacceptable: The HFC blends are R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, and R-507A. In today's final rule, we are changing the status of these ten refrigerants to unacceptable in new supermarkets as of January 1, 2017 (i.e., one year later than proposed), based on information the Agency received concerning timelines for planning new stores; this information implied that contractual arrangements for specific equipment purchases could have already been in place at the time the proposal was issued but that new systems will not be completed by January 1, 2016. A January 1, 2017, status change date will address this concern. We note that systems not ready for use by January 1, 2017 would not be able to use a substitute listed as unacceptable as of that date.

# (1) What other alternatives does EPA find pose lower overall risk to human health and the environment?

A number of other refrigerants are listed as acceptable for new supermarket systems: FOR12A, FOR12B, HFC–134a, IKON A, IKON B, KDD6, R–125/290/134a/600a (55.0/1.0/42.5/1.5), R–407A, R–407C, R–407F, R–410A, R–410B, R–417A, R–421A, R–422B, R–424A, R–426A, R–437A, R–438A, R–448A, R–449A, R–450A, R–513A, R–744, RS–24 (2002 formulation), RS–44 (2003 formulation), SP34E, THR–02, and THR–03.61 In addition, R–717 is listed as acceptable in new supermarkets when used as the primary refrigerant in a secondary loop system.

Several of these alternatives, such as R–407A, R–407F, and R–744, are in widespread use today in supermarket systems in the United States. EPA considers this widespread use as indicative of the availability of these acceptable alternatives. HFC/HFO blends are also entering the market. For instance, R–448A and R–449A are being used in supermarkets in the United States and R–450A is in use in a

supermarket in Spain.<sup>62</sup> The producer of R-450A, Honeywell, indicated in their comments that supply of this acceptable alternative was "soon to become available." They indicated that they have invested in their U.S. facility "to ensure high-volume manufacturing capability for HFO-1234ze(E)," one component of R-450A. The other component, HFC-34a, is widely available from multiple producers and refrigerant suppliers. Honeywell noted that "commercial quantities of HFO-1234yf and HFO-1234ze [are] available today." Likewise, DuPont indicated an increasing supply of HFO-1234vf, a component in a number of acceptable refrigerants for new supermarket systems, specifically R-448A, R-449A and R-513A, amongst other applications discussed below.

In the preamble to the NPRM, 79 FR at 46144, EPA provided information on the risk to human health and the environment presented by the alternatives that are being found unacceptable as compared with other available alternatives. In addition, EPA listed as acceptable R-450A on October 21, 2014 (79 FR 62863) and included information on its risk to human health and the environment. Concurrently with this rule, EPA is also listing R-448A, R-449A and R-513A as acceptable in this end-use category and is including information on their risk to human health and the environment. A technical support document that provides the additional Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for these alternatives may be found in the docket for this rulemaking (EPA, 2015d). In summary, the other available substitutes all have zero ODP and have GWPs ranging from 0 to 2,630. The refrigerants we are finding unacceptable through this action also have zero ODP, but they have GWPs ranging from 2,730 to 3,985. With the exception of R-717, the other available refrigerants have toxicity lower than or comparable to the refrigerants whose listing status is changing from acceptable to unacceptable. Also, with the exception

of R-717, the other available refrigerants, as well as those that we are finding unacceptable, are not flammable. R-717 is classified as B2L (higher toxicity, lower flammability, low flame speed) under the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 34-2013. However, since it is acceptable only for use as the primary refrigerant (i.e., the one housed in the machine room and limited-access condensers) in secondary loops systems, potential exposure is limited to technicians and operators who are expected to have had training on its safe use. Because of this limited access, the fact that R-717 has been used successfully as a refrigerant for over 100 years, and because building codes and OSHA regulations often apply specifically to the use of R-717, EPA previously determined that in this enduse the risk posed with regard to toxicity and flammability is not significantly greater than for other available refrigerants or for the refrigerants we are listing as unacceptable. Some of the refrigerant blends listed as acceptable, as well as some of the substitutes that we are finding unacceptable include small amounts (up to 3.4% by mass) of VOC such as R-600 (butane) and R-600a (isobutane). These amounts are small. and EPA's analysis of hydrocarbon refrigerants show that even when used neat (i.e., as the sole refrigerant, not as a component within a blend) they are not expected to contribute significantly to ground level ozone formation (ICF, 2014e). In the original actions listing these refrigerants as acceptable or acceptable subject to use conditions, EPA concluded none of these refrigerants pose significantly greater risk than for the refrigerants that are not or do not contain VOC. Because the risks other than GWP are not significantly different for the other available alternatives than for those we proposed to list as unacceptable and because the GWP for the refrigerants we proposed to list as unacceptable is significantly higher and thus poses significantly greater risk, we are listing the following refrigerants as unacceptable: HFC-227ea, R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, and R-507A.

 $<sup>^{61}\,\</sup>rm HFC-22$  and several blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production.

<sup>&</sup>lt;sup>62</sup>Cooling Post, 2014. Spanish store first to test new R404A "drop-in." October 5, 2014. Available online at www.coolingpost.com/world-news/ spanish-store-first-to-test-new-r404a-drop-in/.

#### (2) When will the status change?

As explained here and in our responses to comments, EPA is finalizing a change of status date for new supermarket systems of January 1, 2017.

EPA noted in the NPRM, and multiple commenters echoed, that supermarket equipment using some of the acceptable alternatives, notably HFC–134a, R–407A, R–407C, R–407F and R–744, is available today and has been used in supermarkets for several years. While some, but not all, manufacturers argued more time was warranted to develop additional equipment and address performance issues, they did not provide adequate justification or specificity on when such equipment would be available or when such issues would be addressed.

A supermarket system manufacturer believed time was needed to develop contractor training materials. While EPA agrees that training is valuable, we note below that such training is already available and, given that acceptable alternatives have already been implemented in new supermarkets, we do not see the need to delay our proposed status change date for new equipment in this end-use category more than one year.

However, one system manufacturer noted that supermarket plans are developed in time frames that could hinder the proposed status change date of January 1, 2016. EPA understands that such planning is necessary and we are establishing a status change date of January 1, 2017, to accommodate those end users who have already planned changes to their systems or may have plans to manufacture a new system (e.g., for a new store) but that may not have such systems operational in the period between the time this rule is issued and January 1, 2016. As noted earlier, this change in the proposed status change date will affect those end users who are currently in the midst of planning for a new system or a change to their existing system. A new system not ready for use by January 1, 2017, would not be able to use a refrigerant listed as unacceptable as of that date.

#### (b) Retrofit Supermarket Systems

For retrofit supermarket systems, EPA proposed to list, as of January 1, 2016, nine HFC blends as unacceptable: R–404A, R–407B, R–421B, R–422A, R–422C, R–422D, R–428A, R–434A, and R–507A. In today's final rule we are finding these refrigerants unacceptable in retrofit supermarkets as of July 20, 2016.

Consistent with the proposal, this action does not apply to servicing

equipment designed to use these nine refrigerants or servicing equipment that was retrofitted to use those refrigerants before the July 20, 2016, status change date. For example, supermarket systems designed for use with or retrofitted to R–404A or R–507A prior to July 20, 2016, may continue to operate and to be serviced using those refrigerants.

(1) What other alternatives does EPA find pose lower overall risk to human health and the environment?

A number of other refrigerants are listed as acceptable for retrofit supermarket systems: FOR12A, FOR12B, HFC-134a, IKON A, IKON B, KDD6, R-125/290/134a/600a (55.0/1.0/ 42.5/1.5), R-407A, R-407C, R-407F, R-417A, R-417C, R-421A, R-422B, R-424A, R-426A, R-427A, R-437A, R-438A, R-448A, R-449A, R-450A, R-513A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, THR-02, and THR-03.63 A technical support document that provides the additional Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for these alternatives may be found in the docket for this rulemaking (EPA, 2015d).

Several of the alternatives that remain acceptable are in use today in the United States for supermarket system retrofits. While blends such as R–407A and R–407F have become the norm, GreenChill partners also report use of other refrigerants as retrofits in supermarket systems. <sup>64</sup> Also, as noted earlier, R–450A was used to retrofit a supermarket system in Spain (Cooling Post, 2014).

In the preamble to the NPRM, EPA provided information on the risk to human health and the environment presented by the alternatives that are being found unacceptable and those that remain acceptable. In addition, EPA listed R-450A as acceptable on October 21, 2014 (79 FR 62863) and included information on its risk to human health and the environment. Concurrently with this rule, EPA is also listing as acceptable R-448A, R-449A and R-513A and including information on their risk to human health and the environment. As discussed above, the producers of the substitutes that will remain acceptable do not expect supply problems. In summary, the refrigerants

listed above that remain acceptable have zero ODP as do those that we are finding unacceptable. The refrigerants remaining acceptable have GWPs ranging from below 100 to 2,630, lower than the GWPs of the nine blends we are finding unacceptable, which have GWPs ranging from 2,730 to 3,985. All of the refrigerants remaining acceptable have toxicity lower than or comparable to the refrigerants whose listing status is changing from acceptable to unacceptable. None of the refrigerants that remain acceptable or those that are being listed as unacceptable are flammable. Some of the refrigerant blends that remain acceptable and some of those that we are finding unacceptable include small amounts (up to 3.4% by mass) of VOCs such as R-600 (butane) and R-600a (isobutane). Because these amounts are small, and EPA's analysis of hydrocarbon refrigerants shows that even when used neat (100% by mass), they are not expected to contribute significantly to ground level ozone formation (ICF, 2014e), these blends would also not contribute significantly to ground level ozone formation. Because the risks other than GWP are not significantly different for the other available alternatives than for those we proposed to list as unacceptable, and because the GWP for the refrigerants we proposed to list as unacceptable is significantly higher and thus poses significantly greater risk, we are listing the following refrigerants as unacceptable: R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, and R-507A.

EPA regulations have eliminated or will eliminate by 2020 the production and import of HCFC-22. These and other regulations also affect end users who are using CFC-12, R-502, and several HCFC-containing blends such as R-401A, R-402A and R-408A. Therefore, we believe that the impact of this action addressing retrofits will primarily affect those owners who are faced with the choice of continuing to operate systems with a refrigerant that has been phased out of production and import or to switch to a refrigerant listed as acceptable for retrofit at the time the retrofit occurs.

Many retail chains maintain their own stockpile of HCFC–22, for instance by recovering from stores that are decommissioned or retrofitted and using such supplies to service stores that continue to operate with HCFC–22. In addition, over four millions pounds of HCFC–22 has been reclaimed every year since at least 2000 and over seven

 $<sup>^{63}\,\</sup>rm HCFC{-}22$  and several blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production.

<sup>&</sup>lt;sup>64</sup> The GreenChill Advanced Refrigeration Partnership is a voluntary program with food retailers to reduce refrigerant emissions and decrease their impact on the ozone layer and climate change. See

million pounds every year since 2006.65 Equipment operating with ODS refrigerants may continue to do so given the supply of such materials in stockpiles and through the reclaim market. Thus, owners have the option to continue to operate this equipment through its useful life with the refrigerant they are using, such as HCFC-22. Regardless of the continued supply of HCFC-22 and other ODS refrigerants, we believe that the majority of retrofits are planned for reasons other than the supply of the refrigerant currently in use; for instance, owners may decide to retrofit when upgrading to more energy efficient equipment or during planned maintenance overhauls of their stores.

We see that many retrofits are already directed towards lower-GWP blends such as R-407A and R-407F, which are widely available and remain acceptable for such use under today's rule, and not those of the refrigerants whose status will change to unacceptable under today's rule. These two refrigerants (R-407A and R-407F), other available HFC blends, the additional HFC/HFO options that EPA recently listed as acceptable, and other HFC/HFO blends that are being evaluated by chemical producers and equipment manufacturers, as well as the option of continuing to operate with HCFC-22, are sufficient to meet the various features—such as capacity, efficiency, materials compatibility, cost and supply—that affect the choice of a retrofit refrigerant.66

#### (2) When will the status change?

As explained here and in our responses to comments, EPA is establishing a change of status date for retrofit supermarkets of July 20, 2016.

In the NPRM and above, EPA pointed out that retrofits of supermarkets using acceptable alternatives are already occurring. Supermarket Company ABC indicated that their experience with the use of R-407A in retrofits indicates the availability and viability of it and other alternatives. FMI similarly indicated that many of its members have already stopped performing retrofits with refrigerants we are finding unacceptable. EPA considers these comments directly from the supermarket retailer to indicate that adequate performance can be achieved using refrigerants that will remain listed as acceptable.

As indicated in section V.C.1.c above, retrofits may require various changes to

the existing equipment, such as different lubricants, new materials such as gaskets and filter driers, and adjustments to expansion valves. These changes include readily available materials and common refrigeration practices. Such retrofits to acceptable alternatives are already occurring, and the option to continue to operate and service existing systems remains; however, EPA received comment that users may plan a "new store layout" in advance. While not specifically referencing retrofits, a new layout of an existing store may include the retrofitting of the existing supermarket system. Therefore, EPA is modifying the change of status date to provide a full year from publication of the final rule to ensure that any supermarkets that may have retrofits underway using a refrigerant that will no longer be acceptable will be able to complete those retrofits ahead of the change of status date. While EPA did not receive specific comments on the time to complete retrofits that are underway, it is our understanding that any ongoing retrofits can be completed within this timeframe.

(c) How is EPA responding to comments on retail food refrigeration (supermarket systems)?

Comment: Several commenters commented on the proposed January 1, 2016 change of status date for new supermarket systems. One supermarket owner, Supermarket Company ABC, specifically supported the proposed 2016 date for both new and retrofit systems. An industry organization representing supermarkets, FMI, stated that "a majority of our members have already voluntarily and proactively discontinued the use of R-404A, R-507 and R-422D for new systems and as a retrofit refrigerant." Two environmental organizations, NRDC and IGSD, supported the proposed 2016 date for both new and retrofitted supermarket systems. One manufacturer of supermarket systems, Hillphoenix, supported the change of status date of January 1, 2016, for HFC-227ea, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A and R-434A in new and retrofit supermarket systems.67

Several other manufacturers of supermarket equipment, including Hussmann, Master-Bilt, Lennox, and Zero Zone, and an association representing such manufacturers— AHRI—suggested later dates for the change of status. Hussmann suggested a

change of status date of 2018 for new equipment as store layouts of their customers are planned "up to three years in advance." Another manufacturer, Lennox, requested three vears from the date of any final rule, a position supported by AHRI, which also noted "alternatives are available and manufacturers have started re-designing products to minimize or eliminate the use of high GWP refrigerants." Master-Bilt indicated that under the proposed January 1, 2016, change of status date for new supermarket systems, they would convert to HFC-134a and R-407A, but would have to address issues of energy efficiency and reliability. They believed "these HFCs will also be banned as soon as lower GWP alternatives are available" and therefore did not offer a long-term solution. Instead, they stated blends with even lower GWPs than the ones remaining acceptable would be available in 1-3 years and requested a minimum of 3 years from then to develop products. Zero Zone indicated that it has products available for R-407A and R-407C, but needs time to address performance

Response: Several commenters indicated that many stores were already using alternatives other than the ones we proposed to list as unacceptable. While two manufacturers of equipment, Zero Zone and Lennox, and AHRI advocated for a later change of status date, they also indicated that products using refrigerants that will remain acceptable are already in use. Hillphoenix and Hussmann, both of whom offer supermarket systems with such refrigerants, and Supermarket Company ABC and FMI, who have used such products, did not indicate that there were performance, efficiency or reliability issues when using R-407A, R-407C or R-407F in supermarket systems.

We recognize the concern raised by Hussmann regarding store layout plans for new systems. Store design plans are generally developed well in advance of the physical change-over or construction, because of several different factors related to construction and installation as well as the need to address any commissioning, performance optimization or start-up procedures. Hussmann suggested a change of status date of 2018 to allow up to three years for design. Hussmann did not indicate if the "up to three years in advance" for planning a new design was a typical planning cycle or a rare maximum, nor did they indicate that any particular customer currently is in the planning stage but will not have equipment designed to use a refrigerant

<sup>&</sup>lt;sup>65</sup> EPA, 2012a. The latest data on refrigerant reclamation can be found on EPA's Web site at: www.epa.gov/spdpublc/title6/608/reclamation/recsum merged.pdf.

<sup>66</sup> For example, see CCAC, 2012.

 $<sup>^{67}\,</sup> They$  addressed the change of status date for R–404A and R–507A with regard to stand-alone units but not supermarket systems.

we are listing as unacceptable operational until 2018. We further note that the NPRM was proposed on August 6, 2014, and thus supermarkets were on notice at that time that the refrigerants currently listed as acceptable would possibly be unacceptable for use as of January 2016. In order to address concerns about those end users who began planning prior to the proposal, we are establishing a change of status date one year later than proposed for new supermarket systems and July 20, 2016 for retrofits. This will provide those end users who were in the planning stage prior to the time of the proposal over two years after issuance of the proposal to ensure new supermarket systems are in place and operational and likewise approximately two years to complete any retrofits.

Comment: Lennox noted that supermarket system designs exist for R-407 series refrigerants, but stated that manufacturers "need at least 3 years to develop complete product lines, technical literature and contractor training materials." Lennox did not indicate specifically how much time was needed to complete their equipment development. Zero Zone Inc. comments that the industry needs at least six years to make a smooth complete transition away from R-404A, R–507A, and HFC–134a; they indicated this time was needed "to eliminate the performance issues and design product that uses these refrigerants in the most energy efficiency manner." In its comments regarding supermarket systems, AHRI indicated low-GWP alternatives are available and stated research on other, lower-GWP refrigerants was underway but requested "a minimum of 3 years" to transition. AHRI contended that "manufacturers have started re-designing products to

minimize or eliminate the use of high GWP refrigerants" but that

"manufactures need more time" on "the re-design effort that started [a] few years ago." In general comments not specific to the three retail food refrigeration enduse categories addressed in the proposal, AHRI also indicated that "a typical design cycle takes an average 7 years from start to finish" for nonflammable alternatives. Supermarket Company ABC referenced the NPRM discussion of new supermarket systems (79 FR 46144) and stated that their "own experience and testing with R134a, CO<sub>2</sub> and the R-407 series of refrigerants have demonstrated to our satisfaction that implementable alternatives to R-404A and R-507A are available to meet that time frame" of January 1, 2016.

Response: The commenters have not provided sufficient information to support that alternatives will not be available for several years because of technical constraints. As indicated in the comments from AHRI, Lennox, and Zero Zone, manufacturers have been working for the past several years to design systems using low GWP alternatives and as FMI noted many supermarkets are already choosing to use them. EPA noted in the proposal that R-407A systems have already become a norm for supermarkets and Supermarket Company ABC indicated it was using R-407A in its comments. In fact, EPA notes that the amount of R-404A in use from partners participating in EPA's GreenChill partnership program reporting in 2012 and 2013 increased only 1.3%, while the amount of R-407A in use increased 24%. Hence, we do not agree that a several year delay in the change of status date is needed to accommodate design of systems.

With respect to contractor training, EPA agrees proper education and

training is important, and we note that there are already many manufacturers and suppliers who have been conducting such training. For example, Hillphoenix, a manufacturer of supermarket systems and other equipment affected by this rule, operates a learning center with courses available including several on R-744 equipment.68 Learning material is also available from EPA's GreenChill program, including for instance the GreenChill retrofit guidelines,69 which contain material on refrigerants R-407A, R-407F and R-427A, all of which remain acceptable in retrofit supermarket systems. For supermarket systems, we note that alternatives such as R-407A have been in the market and have been used successfully for many years. Other alternatives, such as R-448A, R–449A, R–450A and R–513A, are nonflammable and operate with similar characteristics to HFC-134a or R-404A, and hence should require only minimal extra training. EPA believes the January 1, 2017, change of status date for new supermarket systems, will allow technicians that focus on particular enduses or end-use categories to obtain the training they need and likewise for those that cover all end-uses and enduse categories to build their skills across those end-uses over time. We disagree that a need to develop complete technical lines and technical literature are technical challenges that limit the availability of refrigerants for new supermarket systems beyond January 2017.

3. What is EPA finalizing for retail food refrigeration (remote condensing units)?

The change of status determinations for retail food refrigeration (remote condensing units) is summarized in the following table:

Table 5—Change of Status Decisions for Retail Food Refrigeration (Remote Condensing Units)

End-use	Substitutes	Decision
Retail food refrigeration (remote condensing units) (new).	HFC-227ea, R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, R-507A.	Unacceptable as of January 1, 2018.
Retail food refrigeration (remote condensing units) (retrofit).		Unacceptable as of July 20, 2016.

# (a) New Remote Condensing Units

For new remote condensing units, EPA proposed to list, as of January 1, 2016, nine HFC blends and HFC–227ea as unacceptable. The HFC blends are R– 404A, R–407B, R–421B, R–422A, R– 422C, R–422D, R–428A, R–434A, and R–507A. In today's final rule, we are finding that same list of nine HFC blends and HFC–227ea as unacceptable as of January 1, 2018. The change from the proposal is in response to

information provided by commenters concerning technical challenges with meeting the January 1, 2016, proposed date.

<sup>&</sup>lt;sup>68</sup> See www.hillphoenixlc.com/coursecurriculum/refrigeration-systems/.

<sup>&</sup>lt;sup>69</sup> EPA, 2011b. GreenChill Best Practices Guidelines, Commercial Refrigeration Retrofits. August 2011. This document is accessible at

http://www2.epa.gov/sites/production/files/documents/retrofit\_guideline\_august\_2011.pdf.

(1) What other alternatives does EPA find pose lower overall risk to human health and the environment?

A number of other refrigerants are listed as acceptable for new remote condensing units: FOR12A, FOR12B, HFC–134a, IKON A, IKON B, KDD6, R–125/290/134a/600a (55.0/1.0/42.5/1.5), R–407A, R–407C, R–407F, R–410A, R–410B, R–417A, R–421A, R–422B, R–424A, R–426A, R–437A, R–438A, R–448A, R–449A, R–450A, R–513A, R–744, RS–24 (2002 formulation), RS–44 (2003 formulation), SP34E, THR–02, and THR–03.70 R–717 is acceptable in remote condensing units when used as the primary refrigerant in a secondary loop system.

Some of these acceptable alternatives are currently in use in remote condensing unit systems in the United States, such as R–407C and R–407F. Others, such as R–744 and hydrocarbons, while not indicated as in use in the United States, are being used in limited demonstration trials in Europe and elsewhere. In addition, commenters have pointed out that testing of low-GWP HFC/HFO blends is underway; several of these HFC/HFO blends have been submitted to EPA for SNAP review in this end-use category and four are listed as acceptable.

See section V.C.2.a.1 above for a summary of our comparative assessment of the SNAP criteria (ODP, GWP, VOC, toxicity, flammability) for the refrigerants we are listing as unacceptable with the other available refrigerants. The refrigerants we are listing as unacceptable for new remote condensing units are the same as those we are listing unacceptable for new supermarket systems. Likewise, the other available refrigerants are the same for new remote condensing units as for new supermarket systems. For the same reasons as presented in section 2, EPA concludes that there are other refrigerants for use in new remote condensing units that pose lower overall risk to human health and the environment than the alternatives we are listing as unacceptable.

# (2) When will the status change?

As explained here and in our responses to comments, EPA is establishing a change of status date for new remote condensing units of January 1, 2018.

Blends such as R–407A, R–407C and R–407F are technically viable options. We did not receive any comments suggesting that these or other

alternatives that will remain acceptable could not be used in these systems. In fact, information in the docket to this rule supports the feasibility of these alternatives. For example, information in the Agency's possession from a manufacturer of remote condensing units provides an energy efficiency analysis for R–407A as compared with R-404A in remote condensing units, with results ranging from 10% lower to 1% higher in low-temperature equipment and 0% to 6% higher in medium-temperature equipment (EPA-HQ-OAR-2014-0198-0184). For unit coolers, this information showed improved results of 4.3% to 13.3% in medium-temperature applications. While the low-temperature applications showed 3.6% to 6.7% decreases, it was noted this came "as the capacity increased;" hence, we expect adjustments to the equipment could improve the efficiency while still meeting the original capacity requirements. In addition, Honeywell indicated that R-448A and R-449A, which have been submitted to SNAP for review in this end-use, are undergoing extensive field trials and that R-448A is "close to being qualified with numerous manufacturers," indicating that manufacturers are developing equipment to use this alternative. DuPont indicates that R-449A (also referred to as DR-33 and XP40), which has been submitted to SNAP for review in this end-use, works well in their tests of a display case connected to a remote condensing unit. DuPont found that the energy consumption for this refrigerant in a remote condensing unit originally designed for R-404A was 3% to 4% less than R-404A in low-temperature tests and 8% to 12% less in mediumtemperature tests.

Although there are technically viable alternatives, we recognize the testing and certification needs for this equipment. Compliance with DOE energy conservation standards will be required on March 27, 2017 for commercial refrigeration equipment and on June 5, 2017 for walk-in coolers and freezers (see also section V.C.1.b above and V.C.7 below). Commenters noted the challenges with timing for designing products with acceptable alternatives and testing these products to meet the 2017 DOE energy conservation standards for commercial refrigeration equipment and for walk-in coolers and freezers. EPA agrees with the commenters that the challenge of meeting both this status change rule and the DOE standards creates a significant technical hurdle that would be difficult to overcome by a January 2016 change

of status date. A January 1, 2018, change of status date for remote condensing units recognizes the time needed for redesign and testing to meet both regulatory obligations.

# (b) Retrofit Remote Condensing Units

For retrofit remote condensing units, EPA proposed to list, as of January 1, 2016, nine HFC blends as unacceptable: R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, and R-507A. In today's final rule, we are establishing a change of status date for these refrigerants of July 20, 2016.

Consistent with the proposal, this action does not apply to servicing equipment designed to use these nine refrigerants or servicing equipment that was retrofitted to use those refrigerants before the January 1, 2018 status change date. For example, remote condensing units designed for use with or retrofitted to R–404A or R–507A prior to July 20, 2016, are allowed to continue to operate and to be serviced using those refrigerants.

(1) What other alternatives does EPA find pose lower overall risk to human health and the environment?

A number of other refrigerants are listed as acceptable for retrofitting remote condensing units: FOR12A, FOR12B, HFC–134a, IKON A, IKON B, KDD6, R–125/290/134a/600a (55.0/1.0/42.5/1.5), R–407A, R–407C, R–407F, R–417A, R–417C, R–421A, R–422B, R–424A, R–426A, R–427A, R–437A, R–438A, R–448A, R–449A, R–450A, R–513A, RS–24 (2002 formulation), RS–44 (2003 formulation), SP34E, THR–02, and THR–03.71

Unlike retrofits of supermarket systems, which are common, retrofits of remote condensing units are unusual. However, given that the operating conditions and requirements between supermarket systems and remote condensing units are generally similar, EPA believes blends such as R–407A, R–407C and R–407F are available options.

See section V.C.2.b.1 above for a summary of our comparative assessment of the SNAP criteria (ODP, GWP, VOC, toxicity, flammability) for the refrigerants we are listing as unacceptable with the other available refrigerants. The refrigerants we are listing as unacceptable for retrofit remote condensing units are the same as those we are listing as unacceptable for retrofit supermarket systems. Likewise, the available alternatives for retrofit

 $<sup>^{70}\,\</sup>rm HCFC{-}22$  and several blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production.

 $<sup>^{71}\</sup>mbox{HCFC-}22$  and several blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production.

remote condensing units are the same as those for retrofit supermarket systems. For the same reasons as presented in section V.C.2.b.1, EPA concludes that there are other refrigerants for use in retrofit remote condensing units that pose lower overall risk to human health and the environment than the alternatives we are listing as unacceptable.

EPA regulations have eliminated or will eliminate by 2020 the production and import of HCFC-22. These and other regulations also affect end users who are using CFC-12, R-502, and several HCFC-containing blends such as R-401A, R-402A and R-408A. Therefore, we believe that the impact of this action addressing retrofits will primarily affect those owners who are faced with the choice of continuing to operate systems with a refrigerant that has been phased out of production and import or to switch to a refrigerant listed as acceptable for retrofit at the time the retrofit occurs.

As noted in section V.2.b.1, millions of pounds of HCFC-22 are reclaimed every year, and this supply is available to remote condensing unit owners, operators and technicians, just as it is available for supermarket owners, operators and technicians. We also noted that many retail chains have maintained their own stockpile of HCFC-22, for instance by recovering from stores that are decommissioned or retrofitted and using such supplies to service stores that continue to operate with HCFC-22. This same strategy is possible for those who own or operate multiple facilities using remote condensing units. By establishing a change of status date of July 20, 2016, we are providing owners and operators of remote condensing units the opportunity to begin to address any HCFC-22 supply concerns they may have. Thus, owners have the option to continue to operate this equipment through its useful life with the refrigerant they are using, such as HCFC-22.

Supermarket Company ABC indicated that they have used R-407A to retrofit HCFC–22 systems and that their experience indicates the availability and viability of this and other alternatives. The success of R-407A as a retrofit refrigerant, the other available HFC blends, the additional HFC/HFO options that EPA recently listed as acceptable, and the other HFC/HFO blends that are being evaluated by chemical producers and equipment manufacturers, as well as the option of continuing to operate with HCFC-22, are sufficient to meet the various features—such as capacity, efficiency, materials compatibility, cost

and supply—that affect the choice of a retrofit refrigerant.

#### (2) When will the status change?

As explained here and in our response to comments, EPA is establishing a change of status date for retrofit remote condensing units of July 20, 2016.

We did not receive any comments suggesting that alternatives that remain acceptable could not be used in these systems. As noted above, Supermarket Company ABC indicated that they have had success using R-407A to retrofit HCFC-22 systems. Results from testing of remote condensing units with R-407A and R-449A are presented above in section V.C.3.a.2. Those results showed increased energy efficiency and/or increased capacity with those refrigerants, indicating that they are viable for both new and retrofit equipment. As indicated in section V.C.1.c above, retrofits may require various changes to the existing equipment, such as different lubricants, new materials such as gaskets and filter driers, and adjustments to expansion valves. These changes include readily available materials and common refrigeration practices. Such retrofits to acceptable alternatives are already occurring, and the option to continue to operate and service existing systems remains. However, as discussed in Section V.C.2.b.2 above, comments indicate that a "new store layout" could be planned or otherwise underway, and that such layout may include the retrofitting of existing remote condensing units to a refrigerant that will no longer be acceptable. Therefore, by providing one full year from the final rule's publication, EPA is providing sufficient time for any such retrofits in this end-use category to occur as planned.

(c) How is EPA responding to comments on retail food refrigeration (remote condensing units)?

Comment: Two environmental organizations, NRDC and IGSD, urged EPA to maintain the proposed status change date of January 1, 2016, for new remote condensing units. Supermarket Company ABC stated that they did not oppose the January 1, 2016, change of status date for new remote condensing units. FMI, an industry organization representing supermarkets, a market segment that also utilizes remote condensing units, pointed out that "a majority of our members have already voluntarily and proactively discontinued the use of R-404A, R-507, and R-422D for new systems and as a retrofit refrigerant."

Many equipment manufacturers including: Hussmann; Continental Refrigerator; Nor-Lake; Master-Bilt Products; International Cold Storage, Crown Tonka, and ThermalRite Walk-Ins; Lennox; and Manitowoc requested later dates for the status change ranging from 2018 to 2025. In some cases the date requested applied to new equipment in other end-use categories as well as new remote condensing units. AHRI suggested a minimum of six years to transition. The North American Association of Food Equipment Manufacturers (NAFEM) and Howe Corporation submitted comments that were general rather than specific to any particular refrigeration end-use. Based on NAFEM's membership and the products Howe discussed, EPA believes these comments apply to remote condensing units and stand-alone equipment. Howe proposed that the status of R-404A and R-507A change "no sooner than year 2024" while NAFEM suggested a ten-year delay for all of the refrigeration end-uses addressed in the proposed rule and enumerated 14 tasks that they indicate are "necessary to safely introduce different/flammable refrigerants into the manufacturing process." A separate  $comment \; \bar{N} A FEM \; listed \; \bar{f} ive$ phases, totaling 10 to 12 years, to adopt hydrocarbon refrigerants but also stated that "in no case should any manufacturer be expected to transition prior to 2022." These manufacturers and industry associations cited concerns over the availability of alternatives, the need to design and test products using those alternatives, as well as other concerns that we summarize and address in the Response to Comments Document that has been placed in the docket. Several manufacturers indicated that a January 1, 2016, change of status date would create significant difficulties in designing products with refrigerants that remain acceptable while also meeting the DOE energy conservation standards for commercial refrigeration equipment and for walk-in coolers and freezers that are scheduled to become effective in 2017 (see also section V.C.1.b above and V.C.7 below). In particular, the commenters claimed that additional development of lowtemperature products may be necessary to match current efficiency levels.

Hussmann was concerned with the lead time of its customers in planning store layouts with "remote systems," which could include remote condensing units as well as supermarket systems, and indicated that a date of 2018 would allow its customers to better determine what types of systems and refrigerants

to use. Lennox proposed a "phased in implementation timing by refrigerant equipment end-use category," suggesting five years from publication of the final for remote condensing units compared to three years for supermarkets and seven years for standalone units. AHRI similarly suggested that the change of status date for remote condensing units occur after that of supermarkets.

Regarding HFC/HFO blend alternatives, Honeywell, indicates that supply of R-450A, an alternative listed as acceptable, will be available soon and that R-448A and R-449A, which are currently under SNAP review, are undergoing extensive field trials. Honeywell further stated that R-448A is "close to being qualified with numerous manufacturers," indicating that manufacturers are developing equipment to use this refrigerant. DuPont indicated that R-449A works well in their tests of a display case connected to a remote condensing unit.

Response: Supermarket Company ABC and FMI as well as environmental organizations supported or did not oppose the proposed status change date of January 1, 2016. A number of other commenters supported a later date ranging from 2017 to as late as 12 years after this action is finalized. The comments requesting later status change dates either did not address retrofits or did not provide adequate information indicating why a date earlier than that for new remote condensing units would be infeasible for retrofit equipment.

Although some use of alternatives is already occurring, we agree with the commenters that certain technical challenges still exist that support a change of status date later than we proposed for new and retrofit equipment. However, we do not agree that significant additional time is needed before alternatives listed as acceptable will be available for new equipment.

There are alternatives that are not subject to a status change that are used already in new and retrofit remote condensing units and others are being developed and deployed. As supported by the comments from FMI, many

supermarkets have already transitioned away from the refrigerants we are listing as unacceptable and are using refrigerants that will remain acceptable after this final action. Supermarket Company ABC stated that alternatives were available, pointing towards their experience with R-407A in retrofits and HFC-134a, R-744 and the R-407 series in new equipment. Information in the Agency's possession from a manufacturer of such equipment, explained above, is indicative that R-407A, among other available alternatives, can be readily implemented now in new remote condensing units at mediumtemperature applications both during and after meeting DOE energy conservation standards for commercial refrigeration equipment and for walk-in coolers and freezers. However, the information showed efficiency losses for this refrigerant in low-temperature applications. Although DuPont points to positive results using R-449A in a display case connected to a remote condensing unit, this refrigerant too showed lower energy efficiency in lowtemperature than medium-temperature conditions. Both comments indicate that there is a more significant challenge for low-temperature applications.

Thus, while there has been significant progress in transitioning to alternatives that will remain acceptable in mediumtemperature applications, there has been less progress in doing so for lowtemperature applications. However, the information provided by Honeywell and DuPont indicates that significant additional time will not be needed before equipment is available. In recognition that new remote-condensing unit equipment will need to meet DOE and National Sanitation Foundation (NSF) standards, and some efficiency challenges exist particularly with lowtemperature equipment, we are establishing a status change date of January 1, 2018, for new remote condensing units and July 20, 2016 for retrofits.

Given that the low-temperature results with R-407A showed only 3.6% to 6.7% efficiency declines along with capacity increases, and those from

DuPont with R-449A showed a slight improvement in efficiency, we consider a status change date of January 1, 2018, to be adequate to adopt these or other acceptable alternatives into new equipment and perform any testing and certification necessary. A January 1, 2018, change of status date for new remote condensing units will allow time for manufacturers to redesign any products that require additional engineering to meet both this rule and the DOE standards. In situations where these refrigerants do not show energy efficiency improvements, other design changes as described in the DOE rulemakings and in the literature can be utilized to achieve required efficiencies. In addition, as indicated above, current research and testing on some HFC/HFO blends show similar or better energy efficiency for these products.

While we agree than a short additional amount of time is needed to address these technical challenges and the testing and certification requirements for new equipment, we disagree with commenters who suggest that a lengthy period is needed prior to the change of status. NAFEM estimated 10 to 12 years to adopt hydrocarbon refrigerants; however, as hydrocarbons are not listed as acceptable for remote condensing units, and no schedule was provided for nonflammable refrigerants, EPA views this comment as pertaining to stand-alone equipment. (See section V.C.4 below). All of the refrigerant blends that remain acceptable are nonflammable and some were designed to mimic HFC-134a and R-404A. EPA believes that these can be adopted into manufacturers' products with minor changes while still meeting the DOE requirements. The commenters failed to identify specific technical challenges that would support a more lengthy delay in the change of status date.

4. What is EPA finalizing for retail food refrigeration (stand-alone equipment)?

The change of status determination for retail food refrigeration (stand-alone equipment) is summarized in the following table:

TABLE 6—CHANGE OF STATUS DECISIONS FOR STAND-ALONE EQUIPMENT

End-use	Substitutes	Decision
Retail food refrigeration (stand-alone medium-temperature units <sup>72</sup> with a compressor capacity below 2,200 Btu/hr and not containing a flooded evaporator) (new).	FOR12A, FOR12B, HFC-134a, HFC-227ea, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-426A, R-428A, R-434A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, THR-03.	Unacceptable as of January 1, 2019.

End-use	Substitutes	Decision	
Retail food refrigeration (stand-alone medium-temperature units with a compressor capacity equal to or greater than 2,200 Btu/hr and stand-alone medium-temperature units containing a flooded evaporator) (new).		Unacceptable as of January 1, 2020.	
Retail food refrigeration (stand-alone low-temperature units <sup>73</sup> ) (new).	424A, R-426A, R-428A, R-434A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, THR-03. HFC-227ea, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421B, R-422B, R-422B, R-422C, R-421A, R-421B, R-422A, R-42B, R-422C, R-428B, R-488B, R-48	Unacceptable as of January 1, 2020.	

422D, R-424A, R-428A, R-434A, R-437A, R-438A, R-507A, RS-44 (2003 formulation). R-404A and R-507A .....

TABLE 6—CHANGE OF STATUS DECISIONS FOR STAND-ALONE FOURMENT—Continued

# (a) New Stand-Alone Equipment

Retail food refrigeration (stand-alone units only)

(retrofit).

For new stand-alone equipment, EPA proposed to list HFC-134a and 31 other refrigerants for new stand-alone retail food refrigeration equipment unacceptable, as of January 1, 2016. In today's final rule, EPA is subdividing the new retail food refrigeration (standalone equipment) end-use category. For new stand-alone medium-temperature units with a compressor capacity below 2,200 Btu/hr and not containing a flooded evaporator, EPA is changing the listing for HFC-134a and 30 other refrigerants from acceptable to unacceptable as of January 1, 2019. These 30 other refrigerants are FOR12A, FOR12B, R-426A, RS-24 (2002 formulation), SP34E, THR-03 and 24 additional refrigerants, listed below, for which EPA is changing the status in all types of stand-alone equipment. For new stand-alone medium-temperature units with a compressor capacity equal to or greater than 2,200 Btu/hr and all stand-alone medium-temperature units containing a flooded evaporator, EPA is changing the listing of HFC-134a and the same 30 other refrigerants from acceptable to unacceptable as of January 1, 2020. For new stand-alone lowtemperature units, EPA is changing the status from acceptable to unacceptable of 24 refrigerants as of January 1, 2020. The 24 refrigerants are: HFC-227ea, KDD6, R-125/290/134a/600a (55.0/1.0/ 42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-428A, R-434A, R-437A, R-438A, R-

507A, and RS-44 (2003 formulation). While EPA proposed to change the status from acceptable to unacceptable for FOR12A, FOR12B, HFC-134a, R-426A, RS-24 (2002 formulation), SP34E, and THR-03 in all new stand-alone equipment, EPA is not changing the status for these refrigerants in this final rule in stand-alone low-temperature equipment, or for IKON B for any standalone equipment, for the reasons provided below. EPA clarifies below how the compressor capacity is to be determined as well as how to distinguish medium-temperature and low-temperature stand-alone equipment.

(1) What other alternatives does EPA find pose lower overall risk to human health and the environment?

EPA has listed R-290, R-600a and R-441A acceptable subject to use conditions in new stand-alone equipment. R-290 is already in use globally, including in the United States, and R-600a is in use outside of the United States as well as in test market trials in the United States. For instance, at a recent exposition, stand-alone equipment using R-290 was displayed by multiple companies and component suppliers exhibited compressors, filter driers, controls and expansion valves that are designed to use R-290 or R-

R-450A, R-513A, R-744, IKON A, IKON B and THR-02 are listed as acceptable substitutes in new standalone equipment without use conditions.<sup>75</sup> In addition, HFC-134a,

FOR12A, FOR12B, R-426A, RS-24 (2002 formulation), SP34E and THR-03 remain acceptable without use conditions and are not subject to a change of status date in new stand-alone low-temperature equipment. Also, concurrently with this rule, EPA is listing R-448A and R-449A acceptable without use conditions for new standalone low-temperature equipment. EPA is aware of equipment deployment using R-744 and HFC-134a. We are not aware of such deployment with respect to any other of these substitutes, although we are aware that several are undergoing research and testing. The producer of R-450A, Honeywell, stated that the supply of R-450A is "soon to be available." Although we did not see evidence that products were produced with the HFC/HFO blends that are listed as acceptable, publicly-available literature indicates that R-448A, R-449A, R-450A, R-513A and others are under investigation. For example, R-513A (trade name XP10) was tested in commercial bottle cooler/freezer under test 008 of AHRI's Low-GWP Alternative Refrigerants Evaluation Program research.<sup>76</sup> The Refrigeration and Air Conditioning Magazine quoted Emerson, a major supplier of compressors for this industry, as saying it is "prepared to support customers and devote more resources to qualifying lower-GWP A1 refrigerant alternatives such as R448A, R449A, R-450A and

Unacceptable as of July 20, 2016.

<sup>72 &</sup>quot;Medium-temperature" refers to equipment that maintains food or beverages at temperatures above 32 °F (0 °C).

<sup>73 &</sup>quot;Low-temperature" refers to equipment that maintains food or beverages at temperatures at or below 32 °F (0 °C).

<sup>&</sup>lt;sup>74</sup> See "New regulations inspire hydrocarbon displays at U.S. NAFEM Show, www.hydrocarbons21.com/news/view/6143.

<sup>75</sup> Shecco, 2015. "New Regulations Inspire Hydrocarbon Displays at U.S. NAFEM Show, February 24, 2015. This document is accessible at

http://www.hydrocarbons21.com/news/ viewprintable/6143."

<sup>76</sup> Shapiro, Doron. "System Drop-In Tests of R-134a, R-1234yf, Opteon<sup>TM</sup> XP10, R-1234ze(E), and N13a in a Commercial Bottle Cooler/Freezer" January 25, 2013. This document is accessible at http://www.ahrinet.org/App Content/ahri/files/ RESEARCH/AREP Final Reports/AHRI%20Low-GWP%20AREP-Rpt-008.pdf.

R513A." TPA addressed the supply of these HFC/HFO blends, and specifically the production of HFO–1234yf and HFO–1234ze(E), which are components of these blends, above in section V.C.2.a.1.

In the preamble to the NPRM, EPA provided information on the risk to human health and the environment presented by the alternatives that are being found unacceptable compared with other alternatives, including several refrigerants listed as acceptable (October 21, 2014, 79 FR 62863) or acceptable, subject to use conditions (April 10, 2015; 80 FR 19453) after the NPRM was issued. A technical support document that provides the additional Federal Register citations concerning data on the environmental and health properties (e.g., ODP, GWP, VOC, toxicity, flammability) for the acceptable alternatives as well as those we are finding unacceptable may be found in the docket for this rulemaking (EPA,

In summary, for stand-alone mediumtemperature refrigeration equipment, the substitutes listed above that remain acceptable have zero ODP and GWPs ranging from 1 to about 630. In contrast, the alternatives that we are listing as unacceptable for stand-alone mediumtemperature equipment also have zero ODP and they have GWPs ranging from approximately 900 to 3,985. Three of the substitutes that remain acceptable, R-290, R-600a, and R-441A, are or are composed primarily of VOC. EPA's analysis indicates that their use as refrigerants in this end-use are not expected to contribute significantly to ground level ozone formation (ICF, 2014e). These three substitutes are also flammable; however, the use conditions specified ensure that they do not pose greater overall risk than any of the substitutes currently listed as acceptable in new stand-alone mediumtemperature equipment.<sup>78</sup> None of the refrigerants currently listed as acceptable present significant human health toxicity concerns or other ecosystem impacts. In comparison, the refrigerants we are finding unacceptable are similar in ODP (zero ODP), flammability (low risks of flammability), toxicity (low toxicity), and VOC (non-

VOC or not expected to contribute significantly to ground level ozone formation). Because the risks other than GWP are not significantly different for the other available alternatives than for those we are listing as unacceptable and because the GWP for the refrigerants we are listing as unacceptable is significantly higher and thus poses significantly greater risk, we are listing the following refrigerants as unacceptable for new stand-alone medium-temperature refrigeration equipment: FOR12A, FOR12B, HFC-134a, HFC-227ea, KDD6, R-125/290/ 134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-426A, R-428A, R-434A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, and THR-03.

For stand-alone low-temperature refrigeration equipment, the substitutes that remain acceptable have zero-ODP and GWPs ranging from 1 to about 1,500. The alternatives we are listing as unacceptable have GWPs ranging from approximately 1,800 to 3,985. For the other risk criteria we review, the analysis provided above for stand-alone medium-temperature refrigeration equipment applies also to for the alternatives that remain acceptable and those we are listing as unacceptable. Because the risks other than GWP are not significantly different for the other available alternatives than for those we proposed to list as unacceptable and because the GWP for the refrigerants we proposed to list as unacceptable is significantly higher and thus poses significantly greater risk, we are listing the following refrigerants as unacceptable for new stand-alone lowtemperature refrigeration equipment: HFC-227ea, KDD6, R-125/290/134a/ 600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-428A, R-434A, R-437A, R-438A, R-507A, and RS-44 (2003 formulation).

#### (2) When will the status change?

We are establishing a status change date of January 1, 2019, for new standalone medium-temperature equipment with a compressor capacity below 2,200 Btu/hr and not containing a flooded evaporator, and a status change date of January 1, 2020, for all other types of new stand-alone equipment. For this equipment, there are several alternatives that can meet the technological needs of the market. EIA states that "R-744, R-290, R-441A, and isobutene ('R-600a')

can satisfy the vast majority of the current market for refrigerants in standalone equipment." We are aware of products using R–290, R–600a and R– 744 that are already on the market. According to Shecco, based on its October 2014 survey, the manufacturers of stand-alone equipment they surveyed "are already today able to produce sufficient amount of such R-290, R-600a and R-744] equipment to cover the needs of the entire market. All of the interviewed manufacturers confirmed that they plan to covert [sic] their whole manufacturing facilities to hydrocarbons and/or CO2 by 2018/2019 latest." While the alternatives that remain acceptable will be able to meet the technical constraints for this equipment, time will be needed for the transition to occur. On the aspect of timing, Shecco, Supermarket Company ABC, Hatco, and H&K International suggested a 2018 change of status date, while DuPont and Honeywell suggested 2017. NRDC and IGSD believed EPA should maintain the proposed January 1, 2016, change of status date. In contrast, numerous other manufacturers of stand-alone equipment indicated concerns with hydrocarbons and R-744, and some referenced HFC/ HFO blends as a potential solution. They recommended change of status dates ranging from 2020 to 20 years after the rule becomes final. While we agree that manufacturers will be able to produce equipment using lower-GWP refrigerants addressing a large portion of the market in the period of 2016-2018, we also agree that there are some technical challenges that support a change of status date of 2019 or 2020 for this end-use category.

Manufacturers indicated several necessary steps that will need to occur, including development and testing of components, such as compressors and condensing units, for the full range of stand-alone products. In addition, engineering, development, and testing to meet standards, such as those from UL, DOE and NSF, of the products would start as components became available. Modifications to the factory could be required, ranging from a simpler change of the refrigerant storage area to reconfiguration of the factory to address concerns such as ventilation or other safety measures. Information submitted by the commenters supported that these actions could take a few months or up to a couple of years. However, it is likely that these actions could occur simultaneously with other steps such as equipment design and testing.

Manufacturers identified three distinct refrigerant types. For hydrocarbons, including R–290, we do

<sup>77</sup> Gaved, 2015. "Emerson Climate Technologies offers to help supply chain move to lower-GWP refrigerants," www.racplus.com/news/-emerson-climate-technologies-offers-to-help-supply-chain-move-to-lower-gwp-refrigerants/8677708.article.

<sup>&</sup>lt;sup>78</sup>The risks due to the flammability of these refrigerants in this end-use were analyzed in the SNAP rules finding them acceptable subject to use conditions (December 20, 2011; 76 FR 78832 and April 10, 2015; 80 FR 19453). Refer to Docket ID No. EPA-HQ-OAR-2009-0286 and EPA-HQ-OAR-2013-0748.

not see any question regarding chemical supply. NAMA and True Manufacturing indicated that components have already been designed globally, including in the United States, using both R-290 and R-600a. Danfoss, Manitowoc and Unified Brands indicated that 1–2 years are needed to develop air-cooled condensing units for R-290. Components using other hydrocarbon refrigerants, such as R-441A have not been developed, but these refrigerants are offered for sale in the U.S. and are in ample supply.

EPA believes that much of the component and equipment development can occur at the same time; in other words, as certain components become available, appropriate units could be redesigned using those components, prototypes could be built and tested, and final designs could be produced, while additional components are released. Indeed, it appears that many manufacturers have already identified a portion of their products that they could redesign using R–290, as discussed below. Once product models are designed, testing and certification could

take place.

In summary, to use hydrocarbon refrigerants, such as R-290, the comments support that approximately three and a half years is needed for equipment to become fully available. This includes one to two years to develop additional components beyond those that are currently available and to test the current and newly developed components in models. Equipment development and testing would occur in series, with the final units being developed and ready for testing approximately one year after the components for that unit were available. Testing and certification would likewise occur as products were developed and would span two to three years, much of which while other actions are occurring. We estimate the final units might take an additional six months to a year to test and certify once developed. As discussed above, any required modifications to the factory line and facilities would occur concurrently if a manufacturer chose to use R-290 or another acceptable hydrocarbon refrigerant. Hence, EPA believes that new stand-alone equipment for medium-temperature applications with a compressor capacity below 2,200 Btu/ hr and not containing a flooded evaporator could be available and in compliance with a status change date of January 1, 2019.

The steps in developing products for R–744 would be similar and on a similar time frame as those for hydrocarbons. However, although R-744 is in wide

supply, as supported by commenters such as Hillphoenix, Coca-Cola, Parker-Hannifin, and HC Duke & Son/Electro-Freeze, there has been limited development of components and development of necessary components in a variety of sizes could take two to three years.

Designing stand-alone equipment with R-744 presents challenges such as the need for a complete system redesign due to higher pressures and the different thermodynamic and transport properties. Additionally, as supported by commenters such as HC Duke & Son/ Electro-Freeze, while CO<sub>2</sub> system efficiency is good at lower ambient temperatures, CO<sub>2</sub> system efficiency suffers at higher temperatures. Thus, it may take additional time to develop components and equipment for both medium and low-temperature applications.

Although it may not be feasible to develop R-744 equipment for the full spectrum of stand-alone equipment by a status change date of January 1, 2019, other alternatives, such as the hydrocarbons and HFC/HFO blends would be available for those uses by the January 1, 2019, status change date.

The third group of alternatives is the HFC/HFO blends. Refrigerant producers DuPont and Honeywell provided detailed comments on the development of specific HFC/HFO blends and EPA listed one of these, R-450A, as acceptable in October 2014. Concurrently with this rule, EPA is also listing R-513A as acceptable in all stand-alone equipment and two additional HFC/HFO blends, R-448A and R-449A, acceptable in stand-alone low-temperature equipment.

Some samples of these refrigerants are available today and are being tested, as supported by comments from AHRI. However, supplies of some of these blends are limited at this time because of limits on some of the HFO components, HFO-1234yf and HFO-1234ze(E). However, as discussed above in section V.C.2.a.1, production facilities for these refrigerants have commenced operation and thus, as supported by Honeywell and DuPont, we expect adequate supplies to be available by January 2017 if not before. Unified Brands and Structural Concepts indicated that components for HFC/ HFO equipment are being tested and developed today and Unified Brands further projected that it would be three years for a full line of production-ready components.

HFC/HFO blends found acceptable to date or submitted to the SNAP program are nonflammable, acceptable without use conditions, and designed to mimic

the performance of either HFC-134a or R-404A, refrigerants in predominant use currently. Thus, as compared with hydrocarbons and R-744, there should be fewer technical challenges in developing equipment using these alternatives. Several commenters, including Master-Bilt, Structural Concepts, and Hoshizaki America, supported that transition to these alternatives would be simpler and quicker once components have been developed and there are adequate

supplies.

În summary, should manufacturers choose to pursue HFC/HFO blends, EPA expects such equipment would be widely available in about four years and that R-450A could be available earlier as it was the first such blend found acceptable under SNAP. This includes one to two years for supplies to become widely available, approximately one year for development and testing of components, and approximately one year for equipment development. The short time for development of components and equipment is due to the fact that the properties of the blends are similar to the refrigerants most manufacturers are currently using. Similarly, we expect that there would be limited factory modifications, if any, and that these could occur concurrently with the design work. As with other refrigerants, EPA would expect equipment testing and certification to be rolled out as equipment models are redesigned, with the last units being available approximately six to twelve months after designs are developed.

We are finalizing a status change date of January 1, 2020, for stand-alone lowtemperature retail food refrigeration units; stand-alone medium-temperature retail food refrigeration units with a compressor capacity equal to or exceeding 2,200 Btu/hr; and stand-alone retail food refrigeration units employing

a flooded evaporator.

For these three types of stand-alone equipment, we find that an additional year beyond January 1, 2019, is needed for the change of status. For equipment using a flooded evaporator, Emerson indicated the lower-GWP refrigerants are all "high glide" often in the range of 7 °F to 10 °F (3.9 °C to 5.6 °C), and that such a characteristic presents unique redesign and performance challenges. Because of this unique design challenge that will require additional time to address, we are establishing a January 1, 2020, change of status date for new stand-alone equipment that utilizes a

flooded evaporator. The second segment of the standalone equipment end-use category that we found faced particular technical

challenges was equipment designed to hold products at low temperatures. The choice of refrigerant is in part determined by the desired temperature that food or beverage will be stored. As with "large" equipment, discussed below, commenters, including Hussmann and Hillphoenix, indicated that the charge size limits that apply to the hydrocarbon refrigerants could limit their use in low-temperature equipment, although for some equipment, it may be possible to redesign equipment to use multiple circuits. In addition, these commenters further note that HFC-134a was not a workable refrigerant for lowtemperature applications, and thus some of the HFC/HFO alternatives, specifically R-450A and R-513A, which were designed to perform similarly to HFC-134a, would likewise not be workable in these applications. However, other HFC/HFO alternatives, such as R-448A and R-449A, designed to perform similarly to R-404A could be available for low-temperature uses.

We believe that these technical challenges for stand-alone low-temperature equipment will mean the date upon which technically feasible solutions are available will be later than small, medium-temperature equipment. For this reason, we are finalizing a change of status date of January 1, 2020, for stand-alone low-temperature

equipment. EPA points to the 2014 ASHRAE Handbook on Refrigeration, Chapter 15, which reads "medium-temperature refrigeration equipment maintains an evaporator temperature between 0 and 40 °F [−18 and 4.4 °C] and product temperatures above freezing; lowtemperature refrigeration equipment maintains an evaporator temperature between -40 and 0 °F [-40 and -18°C] and product temperatures below freezing." We believe the product temperature is a more widely understood criteria, especially amongst equipment owners and users and for purposes of compliance, and therefore clarify here that for purposes of this rule "stand-alone medium-temperature equipment" is defined as that which is designed to maintain product temperatures above 32 °F (0 °C) and "stand-alone low-temperature equipment" is defined as that which is designed to maintain product temperatures at or below 32 °F (0 °C).

For large stand-alone equipment with additional cooling capacity requirements, there are challenges with using a number of the lower-GWP refrigerants because the refrigerants are subject to use conditions, including a restriction limiting the charge size to 150 grams per circuit. The charge size

use condition applies to the alternative refrigerants that are the farthest along in design and testing for this end-use category, specifically, R-290 and R-600a. Because larger equipment often needs refrigerant charges that are larger than those provided in the use conditions, we sought comment on possible technical challenges in transitioning to another alternative and asked how charge size limits for these flammable refrigerants might affect our determination of whether and when alternatives that pose lower risk are available for larger equipment. In the NPRM, we sought comment on the possibility of establishing a use restriction that would allow continued use of some refrigerants for which we would otherwise change the status in "large" stand-alone equipment. We sought comment on how we could define "large" and "small" stand-alone units in particular considering charge size.

Several commenters addressed these issues during the comment period. Lennox said that over 98% of its "basic, self-contained refrigeration models exceed 500 grams of refrigerant charge," precluding the use of flammable refrigerants in just one circuit. Manitowoc and Nor-Lake indicated that if they were to use R-290, multiple refrigeration circuits would be required considering the 150 gram use condition that applies to that refrigerant. Some manufacturers discussed the technical difficulties with using multiple circuits. Hillphoenix noted that the use of multiple compressors, each tied to an individual condensing unit, would require "more complex control synchronization that customers must be willing to master" and raised a concern about whether customers would do so. For some equipment, space constraints would limit the practicality of using multiple, separate refrigeration circuits. Minus Forty indicated that "A significant number of our models cannot be or would be very impractical to transition to R-290 due to their size, shape, and custom uniqueness." Nor-Lake stated that multiple circuit equipment would use more energy and believed that the "energy efficiency of a dual system may also create issues with meeting DOE energy requirements.'

EPA agrees that there are additional technical challenges faced in converting this equipment that use large charge sizes. In some instances, the challenge may be in developing multi-circuit systems that use refrigerants subject to the charge-size use limits. In other cases, where multiple circuits are not an option, these manufacturers will need additional time to evaluate refrigerants

R-744 or the newly listed HFC/HFO blends R-448A, R-449A, R-450A and R-513A. Therefore, we have established a later status change date of January 1, 2020, for "large" stand-alone equipment.

A few commenters addressed how EPA could distinguish "small" from "large" stand-alone equipment. Nor-Lake suggested a dividing line and recommended that it could be set based on compressor capacity, pointing to 2,400 Btu/hr and 2,200 Btu/hr for medium and low-temperature freezer systems, respectively. Hillphoenix also recommended looking at refrigerant capacity and performed an analysis that, under specific design prescriptions, indicated the maximum capacity achievable using 150 grams of R-290 would be 4,800 Btu/hr and 1,600 Btu/ hr for medium-and low-temperature applications, respectively. Supermarket Company ABC suggested making a distinction based on interior volume and refrigeration requirements, but did not offer specifics. Southern Case Art indicated difficulty with using R-290 in its products that are open-display units reaching capacities up to 25,000 Btu/hr. Unified Brands indicated R-290 compressors are available to provide cooling capacity up to 5,000 Btu/hr for medium-temperature and 2,000 Btu/hr in low-temperature applications. Traulsen requested a narrowed use exemption for "large stand-alone units requiring 2 or more systems to operate within the 150 gram limit."

We believe that the compressor capacity limits are a reasonable, easilyunderstood and easily-enforceable method to distinguish between products that may be unable to rely on flammable refrigerants or that will face greater challenges in doing so, and those that are more easily able to use flammable refrigerants consistent with the 150gram charge size limits established in the use conditions. We considered separate capacity limits for medium and low-temperature systems as suggested by Nor-Lake and analyzed by Hillphoenix, but determined that establishing just one value would provide more clarity and ease of implementation. We chose the lower of Nor-Lake's capacity of 2,200 Btu/hr as a dividing line and explain how this applies further below. In setting one value, however, we considered the similarity of the capacities suggested by Nor-Lake, and the fact that these came within the range of sizes analyzed by Hillphoenix.

Although the 2,200 Btu/hr compressor capacity delineation was based on the particular comment from Nor-Lake, neither that commenter nor others

indicated how that capacity would be determined. EPA believes consensus standards from AHRI, an association representing manufacturers of such equipment, may be used for this purpose. In today's final rule, we are indicating that the capacity for a standalone unit is to be calculated based on the compressor ratings as determined under AHRI 540-2004, Performance Rating of Positive Displacement Refrigerant Compressors and Compressor Units. Although "capacity" is not a rating specifically to be listed under that standard, we note that "Compressor or Compressor Unit Efficiency" and the "Power Input," which are defined in that standard under clauses 3.1 and 3.4, respectively, are required data for the compressor to be listed, per clause 6.2. The compressor capacity is the product of those two items, with adjustment to ensure the result is in the correct units (i.e., Btu/ hr). Although a range of capacities may be calculated, EPA is clarifying that to determine whether the compressor capacity is equal to or above 2,200 Btu/ hr, we expect the manufacturer to use Table 1 of the standard and choose the "Standard Rating Condition" (defined in clause 3.6.1) most appropriate for the design and intended use of the product. EPA notes that five standard rating conditions are listed in the standard, for instance at Suction Dew Point Temperatures—which is related to the designed food or beverage temperature within the equipment—of 45 °F (7.2 °C), 20 °F (-6.7 °C), -10 °F (-23 °C), -25 °F (-32 °C), and -40 °F (-40 °C). By referring to this table EPA believes the dividing line between "small" and "large" condensing units also considers the product application (e.g., "low" or "medium" temperature), as suggested by Nor-Lake and analyzed by Hillphoenix, and as discussed above.

#### (b) Retrofit Stand-Alone Equipment

For retrofit stand-alone equipment, EPA proposed to change the listing for R–404A and R–507A from acceptable to unacceptable as of January 1, 2016. In today's final rule, we are establishing the change of status date of July 20, 2016.

This action does not apply to servicing existing equipment designed for those two refrigerants or servicing equipment that was retrofitted to use those refrigerants before the January 1, 2016, status change date. For instance, equipment designed for use with or retrofitted to R–404A prior to July 20, 2016, would be allowed to continue to operate using and could be serviced with R–404A.

(1) What other alternatives does EPA find pose lower overall risk to human health and the environment?

While we do not believe retrofits are common in stand-alone retail food refrigeration equipment, a number of refrigerants are listed as acceptable for this purpose: FOR12A, FOR12B, HFC-134a, IKON A, IKON B, KDD6, R-125/ 290/134a/600a (55.0/1.0/42.5/1.5), R-407A, R-407B, R-407C, R-407F, R-417A, R-417C, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-426A, R-427A, R-428A, R-434A, R-437A, R-438A, R-450A, R-513A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, THR-02, and THR-03.79 R-448A and R-449A are also listed acceptable for retrofitting standalone low-temperature units. We also note that many of the refrigerants remaining acceptable are blends with small amounts of hydrocarbons. The hydrocarbon content allows the possibility of retrofitting equipment from an ODS (which would have used alkylbenzene or a mineral oil) without changing the lubricant, whereas usually a polyolester is required when retrofitting to an HFC or HFC blend. Thus we believe these refrigerants are designed for and would prove successful in retrofits of stand-alone equipment, should such a retrofit be desired by the owner.

In the preamble to the NPRM, EPA provided information on the risk to human health and the environment presented by the alternatives that are being found unacceptable compared with other available alternatives. A technical support document that provides the additional Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for these alternatives may be found in the docket to this rulemaking (EPA, 2015d). In summary, the other available alternatives have zero ODP as do those that we are finding unacceptable. However, the refrigerants remaining acceptable have GWPs ranging from below 100 to 3,607, lower than the GWPs of the two blends we are finding unacceptable, which have GWPs of 3,922 and 3,985. All of the refrigerants remaining acceptable have toxicity lower than or comparable to the refrigerants whose listing status is changing from acceptable to unacceptable. The other available refrigerants, as well as those we are finding unacceptable, are not flammable. None of the alternatives is considered a VOC; however, some of the

other available refrigerant blends include small amounts (up to 3.4% by mass) of VOC such as R-600 (butane) and R-600a (isobutane). However, these amounts are small, and EPA's analysis of hydrocarbon refrigerants shows that even when used neat, they are not expected to contribute significantly to ground level ozone formation (ICF, 2014e). Because the risks other than GWP are not significantly different for the other available alternatives than those we are listing as unacceptable and because the GWP for the refrigerants we are listing as unacceptable is significantly higher and thus poses significantly greater risk, we are listing the following refrigerants as unacceptable for retrofit stand-alone refrigeration equipment: R-404A and R-507A.

#### (2) When will the status change?

Commenters did not indicate any technical challenges in retrofitting stand-alone equipment with the refrigerants that remain acceptable. In fact, EIA felt "The poor energy efficiency performance of R-404A is another compelling reason to delist this refrigerant and replace it with R-134a for retrofits, which by comparison, has shown a 10 percent efficiency gain." EPA does not believe retrofits are nearly as common for stand-alone equipment as for other retail food refrigeration uses considered in this final rule, particularly supermarket systems. However, similar to the other types of retail food refrigeration addressed today, EPA is providing one year to ensure that any retrofits that are already underway will have sufficient time to be completed. Therefore, we are establishing a change of status date of July 20, 2016.

(c) How is EPA responding to comments on retail food refrigeration (stand-alone equipment)?

Comment: One commenter, Honeywell, addressed the status change date for retrofits and supported the proposed date of January 2016.

Commenters suggested a wide-range of dates for the status change for new equipment. NRDC and IGSD urged EPA to maintain the proposed status change date of January 1, 2016 for new standalone units. These commenters pointed out that coolers using transcritical R–744 have already been developed. Unified Brands stated "it will be impossible to convert all our equipment from R134a and R404A to R290 by 2016."

A number of commenters supported a change of status a year or two later than that proposed. Two refrigerant

 $<sup>^{79}\,\</sup>rm HCFC{-}22$  and several blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production.

producers, Honeywell and DuPont suggested a change of status date of 2017 for new equipment to allow fuller development of HFC/HFO blends that require minimal design changes and offer similar or better performance than current refrigerants. Shecco indicated that a date of January 1, 2018, was needed for "smaller" manufacturers to meet the requirements. Supermarket Company ABC also supported a 2018 change of status date for new standalone equipment. H&K International indicated R-290 is very energy efficient and that 2018 would provide enough time to transition. Another manufacturer, Hatco, also believed a "January 1, 2018 implementation date would provide the needed time to do the necessary testing and certification for a safe and effective conversion."

Other commenters supported a much later change of status date for new equipment. Approximately 30 manufacturers, two industry associations representing equipment manufacturers (AHRI and NAFEM), an association representing supermarkets (FMI), and a beverage supplier (Coca-Cola) suggested dates ranging from 2020 to 2025. True Manufacturing, indicated they have been shipping products using hydrocarbons and R-744 for several years. Hillphoenix provided a refrigerant change schedule that discussed the development of R-744, hydrocarbons and HFO blends; this schedule suggested various dates for different tasks for these three refrigerant types. Based on the timeframes associated with these tasks, they suggested a change of status date of January 1, 2022, for stand-alone equipment. Lennox believed the NPRM "generally contemplates a wholesale switch to hydrocarbon refrigerants" in stand-alone equipment. NAFEM indicated it would "take ten to twelve years for manufacturers to convert their product lines to use isobutene or propane."

Response: As provided above in our discussion of the status change dates we are finalizing, we agree with the commenters who suggest a few additional years are needed for the status change. However, we do not agree that commenters advocating a lengthy delay in the change of status provided support for such a delay. As an initial matter, to the extent that these commenters identified concerns with alternatives, their concerns were focused on one refrigerant or class of refrigerants and the commenters did not consider the full range of available or potentially available refrigerants. Specifically, those comments appeared to have focused on alternatives for

which the most significant amount of design changes would be necessary and did not appear to consider the range of available refrigerants, many of which could be used with less significant changes to designs. Manufacturers will likely select different refrigerants for different products. Those manufacturers that are not interested in designing equipment that uses hydrocarbon refrigerants, given some of their stated concerns with overcoming challenges with safety and VOC issues, could select a nonflammable fluorinated refrigerant such as an HFC/HFO blend designed to mimic many of the characteristics of the refrigerants they are using today. EPA believes such HFC/HFO blends will become available by the status change dates established in this rule and note that R-448A, R-449A, R-450A and R-513A are listed as acceptable in this end-use category, with the latter two being acceptable in stand-alone medium-temperature equipment and all four being acceptable in stand-alone low-temperature equipment. Furthermore, EPA points to the fact that new HFC/HFO blends have been listed as acceptable and that such blends perform similarly to traditional refrigerants and have proved to be as efficient or even offer an efficiency advantage. As discussed above, the supply of these refrigerants is increasing and the components to use them are in development. EPA believes that by finalizing a status change date for new stand-alone equipment several years later than proposed, manufacturers will have the ability to choose such HFC/ HFO blends for their equipment, as well as the other alternatives, including R-290, R-441A, R-600a and R-744, which have already been listed as acceptable or acceptable, subject to use conditions. There is ample supply of R-290 and R-744; however, the technical difficulties discussed with R-290 (particularly in "large" units) and R–744 suggest that not all manufacturers will be able to convert their products and undergo the testing and certification necessary before that equipment can be sold. Because the HFC/HFO blends are designed to mimic the performance of the refrigerants they replace, the adoption of those is expected to take less time; however, there is only limited supply of those refrigerants now. Given the limited current supply, the initiation of the product conversion, testing and certification would not start until approximately 2016-2017, and hence manufacturers would not be able to provide products using these alternatives until approximately 2019-2020.

As pointed out by Honeywell and DuPont, some of the HFC/HFO blend alternatives, such as R-448A, R-449A, R-450A and R-513A, can be used with little adjustment to existing designs, show energy efficiencies equal to or better than current refrigerants. While there is not currently sufficient supply of these refrigerants, Honeywell and DuPont have indicated that production facilities for the components are on-line (see V.C.2.a.1 above) and that the blends will be made available after listed acceptable with SNAP. As noted previously, Honeywell has stated that R–450A supplies will be "available soon" and multiple component manufacturers are developing equipment that uses these alternatives. Hillphoenix's refrigerant change schedule indicates that "Lab/User Testing" and "Test & Verification" is already underway with such blends. These blends offer equipment manufacturers additional energy efficient options to rapidly transition out of refrigerants listed as unacceptable while also avoiding some of the concerns (e.g., flammability, charge size limits, operation in hot temperatures) manufacturers indicated exist with other alternatives such as R-290 and R-744.

Several commenters pointed out that at least some part of their product line can be converted to R-290 and some manufacturers are already offering products to the market using these options. For instance, Hillphoenix's refrigerant change schedule indicates that the step of "Convert Products" for "Hydrocarbons (on applicable systems)" can begin in 2015 and continue after that until 2020. They did not provide a full explanation of why the process would continue until 2020; however, EPA sees from commenters that there will be time necessary to develop products and have them undergo the testing and certification necessary to sell such products. EPA believes that by our status change dates of 2019 and 2020, and not before, manufacturers will be able to complete the development of products using R-290 or other hydrocarbons. EPA also believes that testing and certification resources are available to meet this deadline, and that more can be created if there is a demand for them.

As many commenters pointed out, compliance with new DOE energy conservation standards for certain commercial refrigeration equipment is required on March 27, 2017 and for stand-alone walk-in coolers and freezers is required on June 5, 2017 (see also sections V.C.1.b and V.C.7). EPA is establishing change of status dates of

January 1, 2019, or January 1, 2020, for stand-alone units. This allows additional time after compliance is required with the DOE standards for manufacturers to potentially redesign any products that require additional engineering to meet both this rule and the DOE standards. With 2019 and 2020 change of status dates, manufacturers have the opportunity to integrate low-GWP refrigerants in their models now as they prepare for the DOE requirements for some or all of their products. Other

products already meeting those DOE standards but utilizing refrigerants that we are listing as unacceptable may be redesigned after the DOE deadline to ensure compliance with both EPA and DOE requirements. Given that some HFC/HFO blends, such as R–450A and R–513A, were designed to mimic HFC–134a in medium-temperature refrigeration, and others, such as R–448A and R–449A, were designed to mimic R–404A in low-temperature refrigeration, EPA believes that these

can be adopted into manufacturers' products with minor changes while still meeting the DOE requirements, once supplies of those refrigerants are made available to the manufacturers.

5. What is EPA finalizing for vending machines?

The change of status determination for vending machines is summarized in the following table:

TABLE 7—CHANGE OF STATUS DECISIONS FOR VENDING MACHINES

End-use	Substitutes	Decision
Vending machines (new only)	FOR12A, FOR12B, HFC-134a, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-410A, R-410B, R-417A, R-421A, R-422B, R-422C, R-422D, R-426A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), SP34E.	Unacceptable as of January 1, 2019.
Vending machines (retrofit only)	R-404A, R-507A	Unacceptable as of July 20, 2016.

## (a) New Vending Machines

EPA proposed to change the listing for HFC–134a and 20 other refrigerants for new vending machines from acceptable to unacceptable as of January 1, 2016. In today's final rule, EPA is changing the listing for HFC–134a and 19 other refrigerants for new vending machines from acceptable to unacceptable as of January 1, 2019. While EPA proposed to change the status from acceptable to unacceptable for IKON B, EPA is not changing the status for this refrigerant in this final rule for the reasons provided below.

The 19 other refrigerants in addition to HFC–134a are: FOR12A, FOR12B, KDD6, R–125/290/134a/600a (55.0/1.0/42.5/1.5), R–404A, R–407C, R–410A, R–410B, R–417A, R–421A, R–422B, R–422C, R–422D, R–426A, R–437A, R–438A, R–507A, RS–24 (2002 formulation), and SP34E.

(1) What other alternatives does EPA find pose lower overall risk to human health and the environment?

A number of other refrigerants are acceptable or acceptable subject to use conditions for new vending machines: IKON A, IKON B, R–290, R–441A, R–450A, R–513A, R–600a, R–744, and THR-02.80

In the NPRM, EPA provided information on the risk to human health and the environment presented by the alternatives that are being found unacceptable and those that remain acceptable. Subsequent to the issuance of the proposal, EPA listed R–290, R–

441A and R-600a, as acceptable, subject to use conditions (April 10, 2015, 80 FR 19453). In addition, concurrently with this rule, EPA is listing R-450A and R-513A acceptable in new vending machines. A technical support document that provides the additional Federal Register citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for these alternatives may be found in the docket for this rulemaking (EPA, 2015d). In summary, the other available refrigerants for new vending machines have zero ODP and GWPs ranging from 1 to about 630. In contrast, those we are finding unacceptable have GWPs ranging from approximately 1,100 to 3,985. IKON B, which we proposed but are not finalizing to be unacceptable, has a GWP around 600. R-290, R-600a, and R-441A are or are composed primarily of VOCs. We have exempted R-290, R-600a and R-441A used in vending machines from the venting prohibition (80 FR 19453). EPA's analysis indicates that their use as refrigerants in this end-use are not expected to contribute significantly to ground level ozone formation (ICF, 2014e). These three substitutes are also flammable; however, the use conditions specified ensure that they do not pose greater overall risk than any of the substitutes currently listed as acceptable in new vending machines.81 None of the refrigerants currently listed as acceptable present significant human health toxicity concerns or other

ecosystem impacts. In comparison, the refrigerants we are finding unacceptable are similar in ODP (zero ODP), toxicity (low toxicity), and VOC (non-VOC or not expected to contribute significantly to ground level ozone formation). When the three hydrocarbon substitutes are used in accordance with the use conditions, their flammability risks are not significantly greater than those of the unacceptable alternatives. Because the risks other than GWP are not significantly different for the other available alternatives than those we are listing as unacceptable and because the GWP for the refrigerants we are listing as unacceptable is significantly higher and thus poses significantly greater risk, we are listing the following refrigerants as unacceptable for new vending machines: HFC-134a, FOR12A, FOR12B, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-410A, R-410B, R-417A, R-421A, R-422B, R-422C, R-422D, R-426A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), and SP34E.

## (2) When will the status change?

EPA is establishing a change of status date for the specified HFC refrigerants in new vending machines of January 1, 2019.

For new vending machines, there are several alternatives that can meet the technological needs of the market. EIA states that "R-744, R-290, R-441A, and isobutene ('R-600a') can satisfy the vast majority of the current market for refrigerants in . . . vending machines." We are aware of products using R-290 and R-744 that are already in use. According to Shecco, based on its October 2014 survey, the manufacturers

 $<sup>^{80}\,\</sup>rm HCFC{-}22$  and some blends containing HCFCs are also listed as acceptable but their use is severely restricted by the phasedown in HCFC production.

<sup>&</sup>lt;sup>81</sup>The risks due to the flammability of these refrigerants in this end-use were analyzed in the SNAP rule finding them acceptable, subject to use conditions (April 10, 2015; 80 FR 19453). Refer to Docket ID No. EPA–HQ–OAR–2013–0748.

of vending machines they surveyed "are already today able to produce sufficient amount of such equipment [R-290 and R-744] to cover the needs of the entire market. All of the interviewed manufacturers confirmed that they plan to covert [sic] their whole manufacturing facilities to hydrocarbons and/or CO2 by 2018/2019 latest." While the alternatives that remain acceptable will be able to meet the technical constraints for this equipment, time will be needed for the transition to occur. On the aspect of timing, Shecco supported a status change date of January 1, 2018, although their survey suggested some manufacturers might not convert until 2019. Shecco indicated that the supply of HFC-free vending machines has been increasing over the last two years. Other commenters suggested that four to five vears would be required, mentioning in particular the supply of components as a major obstacle in achieving the proposed January 1, 2016, status change date. While we agree that manufacturers will be able to produce equipment using lower-GWP refrigerants addressing a large portion of the market in the period of 2016-2017, we also agree that there are some technical challenges that support a change of status date of 2019 for this end-use.

Commenters indicated several necessary steps that will need to occur, including development and testing of components, such as compressors, for the full range of vending machines. In addition, engineering, development, and testing to meet standards, such as those from DOE, of the products would start as components became available. Modifications to the factory could be required, ranging from a simpler change of the refrigerant storage area to reconfiguration of the factory to address concerns such as ventilation or other safety measures. Information submitted by the commenters supported that for the portion of the vending machines that have not already transitioned to a lower-GWP refrigerant, these actions could take a few months or up to a couple of years. However, it is likely that these actions could occur simultaneous with other steps such as equipment design and testing.

One manufacturer identified two refrigerant types: R-744 and hydrocarbons. Refrigerant producers also pointed towards HFC/HFO blends as a third group. For R-744, we do not see any question regarding refrigerant supply. Information submitted by the commenters support that some components are already available. Coca-Cola indicated time was needed for testing and certifying new models of vending machines; however, additional

information indicated that various types of R-744 vending machines are already available or are expected to be available by January 1, 2016. Pepsi has testmarketed R-744 vending machines in the United States as early as 2009.82 The Automated Merchandising Systems (AMS) however stated that R-744 was unlikely as a viable substitute for its equipment, especially for the perishable food vending machines it offers. Although EPA did not see the technical detail to allow us to conclude that R-744 would not be a viable choice for such equipment, we agree that additional time beyond our proposed status change date is needed to explore that and other acceptable substitutes for this equipment. The comments support that equipment can be designed, tested and certified using R-744 by January 1, 2019.

Comments also supported that some components and equipment using hydrocarbons are available. AMS stated that one hurdle for using R-290 is finding 120-volt, 60-hertz components for the U.S. and Canadian markets. AMS also echoed the concern of Coca-Cola that more time is needed for testing and certifying new models of vending machines. EPA agrees time beyond the originally proposed January 1, 2016, status change date is necessary for further development of R-290 components and for necessary testing and certification of R-290 vending machines. Information in the comments indicate that some R-290 components are available from multiple suppliers and we believe that these components could be employed in vending machines.

In summary, to use hydrocarbons refrigerants, comments support that approximately three and a half years are needed for equipment to become fully available. This includes six months to test and design products using the available R-290 components and an additional year to two years for development of other components and equipment designs. Equipment development and testing would occur in series, with the final units being developed and ready for testing approximately six months after the components for that unit were available. Testing and certification would likewise occur as products were developed and would span up to three years, much of which while other actions are occurring. We estimate the final units might take

an additional six months to test and certify once developed. As discussed above, any required modifications to the factory line and facilities would occur concurrently if a manufacturer chose to use R–290 or another acceptable hydrocarbon refrigerant. Hence, EPA believes that new vending machines could be available and in compliance with a status change date of January 1, 2019.

Comments also support that other options besides R-744 and hydrocarbons may be explored for those products that have not yet transitioned. Concurrently with this rule, EPA is listing two HFC/HFO blends, R-450A and R-513A, as acceptable for new vending machines. Although commenters did not indicate a current supply of components for these refrigerants, information indicates that component suppliers are committing additional resources to develop them. EPA believes their adoption can happen quickly as they are both nonflammable blends and are designed to mimic the performance of HFC-134a, the only refrigerant indicated by a manufacturer as used in its vending machines. As noted earlier, Honeywell, the producer of R-450A, indicated that it will be supplying that refrigerant soon. We expect that the refrigerant producers will be able to fully supply these blends in a year or two. EPA expects that components designed for the vending machine market using one or both of these blends could be developed within the next year to eighteen months as more refrigerant supplies become available. As components become available, additional design and testing in vending machines could begin. Because the comments indicated only one refrigerant to be replaced, and because the HFC/HFO blends are designed to mimic that refrigerant, equipment development time for vending machines is expected to be shorter than other end-uses, perhaps adding only six months. Limited factory modifications, if any, could happen concurrently with the design work. As with other refrigerants, EPA would expect equipment testing and certification to be rolled out as equipment models are redesigned, with the last units being available approximately six months after designs are developed.

In summary, we find that HFC/HFO blends could be implemented to meet the January 1, 2019, status change date for new vending machines.

## (b) Retrofit Vending Machines

For retrofit vending machines, EPA proposed to change the listing for R-

<sup>&</sup>lt;sup>82</sup> PepsiCo, 2009. "PepsiCo Brings First Climate-Friendly Vending Machines to the U.S.," March 30, 2009, this document is accessible at www.pepsico.com/live/pressrelease/pepsico-bringsfirst-climate-friendly-vending-machines-to-the-183302009

404A and R–507A from acceptable to unacceptable as of January 1, 2016. In today's final rule, we are finalizing a change of status of July 20, 2016 similar to the retail food end-uses considered in this final action. EPA does not believe retrofits are nearly as common in vending machines as for some of the retail food refrigeration uses, particularly supermarket systems. However, similar to the retail food refrigeration addressed today, EPA is providing one year to ensure that any retrofits that are already underway, will have sufficient time to be completed.

This action does not apply to servicing existing equipment designed for those two refrigerants or servicing equipment that was retrofitted to use those refrigerants before the January 1, 2016, status change date. For instance, vending machines designed for use with or retrofitted to use R–404A or R507A prior to July 20, 2016, would be allowed to continue to operate using and could be serviced with that refrigerant.

(1) What other alternatives does EPA find pose lower overall risk to human health and the environment?

A number of refrigerants are acceptable for retrofitting vending machines: FOR12A, FOR12B, HFC–134a, IKON A, IKON B, KDD6, R–125/290/134a/600a (55.0/1.0/42.5/1.5), R–407C, R–417A, R–417C, R–421A, R–422B, R–422C, R–422D, R–426A, R–437A, R–438A, R–448A, R–449A, R–450A, R–513A, RS-24 (2002 formulation), SP34E, and THR-02.83

We do not believe retrofits are common in vending machines. Many of the refrigerants remaining acceptable are blends with small amounts of hydrocarbons. The hydrocarbon content allows the possibility of retrofitting equipment from an ODS (which would have used alkylbenzene or a mineral oil) without changing the lubricant, whereas usually a polyolester is required when retrofitting to an HFC or HFC blend. Thus we believe these refrigerants would prove successful in retrofits of vending machines, should such a retrofit be desired by the owner.

In the preamble to the NPRM, EPA provided information on the risk to human health and the environment presented by the alternatives that are being found unacceptable and those that remain acceptable. A technical support document that provides the additional **Federal Register** citations concerning data on the SNAP criteria (e.g., ODP, GWP, VOC, toxicity, flammability) for

these alternatives may be found in the docket for this rulemaking (EPA, 2015d). In summary, other alternatives have zero ODP and have GWPs ranging from below 100 to 3,085, lower than the GWPs of the two blends we are finding unacceptable, which have GWPs of 3,922 and 3,985. All of the refrigerants remaining acceptable have toxicity lower than or comparable to the refrigerants whose listing status is changing from acceptable to unacceptable. None of the refrigerants that remain acceptable or those that are being listed as unacceptable is flammable. None of the alternatives is considered a VOC; however, some of the refrigerant blends that remain acceptable include small amounts (up to 3.4% by mass) of VOCs such as R-600 (butane) and R-600a (isobutane). However, these amounts are small, and EPA's analysis of hydrocarbon refrigerants show even when used neat they are not expected to contribute significantly to ground level ozone formation (ICF, 2014e). Because the risks other than GWP are not significantly different for the other available alternatives than those we are listing as unacceptable and because the GWP for the refrigerants we are listing as unacceptable is significantly higher and thus poses significantly greater risk, we are listing the following refrigerants as unacceptable for retrofit vending machines: R-404A and R-507A.

## (2) When will the status change?

Commenters did not indicate any technical challenges in retrofitting vending machines with the refrigerants that remain acceptable. In fact, EIA felt "The poor energy efficiency performance of R–404A is another compelling reason to delist this refrigerant and replace it with R-134a for retrofits, which by comparison, has shown a 10 percent efficiency gain." As discussed above, however, commenters indicated that plans may be underway and that adequate time should be given to allow for those plans to be implemented or changed. Therefore, we are establishing a change of status date of July 20, 2016.

(c) How is EPA responding to comments on vending machines?

Comment: Honeywell supported the proposed date for retrofit vending machines. Regarding new vending machines, NRDC and IGSD believed the proposed status change date of January 1, 2016, was feasible and stated that the Consumer Goods Forum has pledged to transition completely out of HFC equipment by the end of 2015. Honeywell and DuPont, suggested a

change of status date of 2017 for new vending machines to allow fuller development of additional alternatives that would require minimal design changes and offer similar or better performance than current refrigerants. Shecco felt that while the large manufacturers could meet the proposed date, a date of January 1, 2018, would allow for smaller manufacturers to meet the requirements. The Coca-Cola Company claimed the change of status date for new vending machines should be no earlier than January 1, 2020, to allow time for the development of additional compressor models of its preferred alternative to cover a full range of required capacities. AMS, a vending machine manufacturer, believes that one option that is being pursued on the beverage side, R-744, is not a viable solution for perishable food vending equipment. This manufacturer recommends a January 1, 2020, change of status date to allow for development of additional alternatives. The National Automatic Merchandising Association (NAMA) indicated that the conversion timeline is likely to be four or five years, although some of its members estimate the timeline to be as much as eight years, based on the experience of the mid-1990s when companies phased out the use of CFC-12.

Response: We acknowledge the comment supporting the proposed date of January 1, 2016 for retrofit vending machines and note that we are finalizing that change of status date as proposed.

We do not agree with NAMA that the switch away from CFC-12 in the mid-1990s supports a four, five or even eight year period. The phaseout of CFC-12 consumption was January 1, 1996, less than two years after the initial SNAP listings were issued. Regardless, each transition is unique and the timing for transitions can vary end-use by end-use and even for the same end-uses depending on a number of factors, such as whether alternatives that perform similarly to the current refrigerant can be used or whether significant design changes may need to occur.

Regarding this current action for vending machines, the transition away from the substitutes we are listing as unacceptable is already underway based on public commitments made by some of the largest purchasers of vending machines. Shecco conducted a survey of vending machine manufacturers in October 2014 and found that all were planning to convert to hydrocarbons and/or R–744 in the 2018/2019 timeframe at the latest. Many companies have already made significant progress. For example, the Coca-Cola Company has placed over 1.4 million HFC-free

<sup>&</sup>lt;sup>83</sup> HCFC–22 and several blends containing HCFCs are also listed as available but their use is severely restricted by the phasedown in HCFC production.

units globally and EIA indicates that "Pepsi is approaching 1 million hydrocarbon vending machines which use 20 percent less energy than Energy Star requirements." There has been success developing and deploying vending machines with R-744, including the manufacture of components for those machines. EIA enumerated four manufacturers offering hydrocarbon compressors and components for light commercial uses, including vending machines. Although Coca-Cola requested a 2020 change of status date, other information listing commercialization plans for low-GWP stand-alone equipment and vending machines indicated that by January 1, 2016, all of the vending machines in that list were expected to be available with low-GWP refrigerants. However, other commenters indicated that more components need to be developed for different types of vending machines to support a complete transition. AMS stated that more components for R-290 suitable for the U.S. and Canadian power supply (e.g., 60 Hz) were needed. We agree that the choice of components to-date has been limited but we see that it is growing and expect it to continue to grow, especially considering that two large U.S. purchasers of vending machines have committed to move to non-HFC technologies. R-744, R-290 and R-600a components used in other products, like stand-alone retail food refrigeration equipment, may also be adaptable for vending machines.

Thus, although significant progress has been made, in particular with the use of R-744 in vending machines that dispense canned beverages, it is necessary to provide some additional time beyond the proposed date of January 1, 2016 to allow further development of components for different types of vending machines and also to allow further development of components using other alternative

refrigerants.

6. General Comments on the Retail Food Refrigeration and Vending Machine End-Uses

### (a) Specific Numerical Limits for GWP

Comment: Unisom Comfort Technologies requested that EPA consider banning all refrigerants with GWP greater than 10, as there are very many existing alternatives. DuPont recommended that EPA change the status to unacceptable for all alternatives which generally have GWPs above 1,500, such as the R-407 series refrigerants. They suggested this limit "for new and retrofit refrigeration and vending applications." DuPont

indicated that by January 1, 2017, there will be multiple low-GWP alternatives commercially available. Another refrigerant producer, Honeywell, recommended a GWP limit for new supermarket systems and remote condensing units of 1,500 and a GWP limit of 2,000 for retrofitted equipment, based on the IPCC's Fifth Assessment Report (AR5). For new stand-alone equipment and vending machines, Honeywell recommended a GWP limit of 600 (using AR5 GWPs) for HFC-134a replacements and 1,500 for R-404A replacements. CARB suggested adding an additional restriction for all commercial refrigeration to find unacceptable all HFCs with a GWP greater than 1,500 starting in 2018 and all those with a GWP greater than 150 in 2023. Unison Comfort Technologies implored us to "seriously consider banning all refrigerants with GWP>10."

Response: EPA's proposal was limited to determinations for the specific refrigerants proposed which pose significantly greater risk than other available refrigerants, and we cannot take final action changing the status of additional refrigerants without first providing notice and an opportunity for comment. EPA may consider whether to include additional refrigerants in a future proposed status change rule in which EPA would provide the necessary analysis of the SNAP criteria and an opportunity for public comment.

Regarding the suggestion that we establish a specific numerical limit for GWP, as noted in Section IV.B, the structure of the SNAP program, which is based on a comparative framework of available substitutes at the time a decision is being made, does not support the use of such limits. We note that in making our decision for new and retrofit supermarket systems and remote condensing units, EPA pointed to the multi-year history of the successful use of some blends that remain acceptable to support the "availability" of alternatives that pose less risk than those we are listing as unacceptable. Many of these blends have GWPs higher than the limits recommended by the commenters. Thus, at this time, we do not believe an analysis of refrigerants below those limits recommended by the commenters with those above the limit and which remain acceptable would support a conclusion that the lower-GWP refrigerants are available for use, as many have not been demonstrated to be technically feasible for products and systems in these specific end-use categories. As noted previously, there are a number of technical challenges that must be addressed in selecting a refrigerant for use in a specific system

and we do not have information supporting use of these lower-GWP refrigerants. However, as we see from the current action, the refrigeration industry has made great progress in the last five to ten years in moving toward lower-GWP alternatives and we see that momentum continuing. Therefore, it is possible that at some future date, we could determine to list additional alternatives as unacceptable based on a determination that there are lower-GWP alternatives available that, based on consideration of the SNAP review criteria, pose lower overall risk.

### (b) Comments and Responses Concerning Small Businesses

Comment: Commercial Food **Equipment Service Association** (CFESA), an organization representing service companies and technicians, suggested a timeline "ideally extended to 10 years for small businesses" and "no less than 5 years" for large companies. Shecco believed that many of the smaller manufacturers lag behind the larger companies in the switch away from HFC-134a in stand-alone equipment and vending machines. They suggested a January 1, 2018, change of status date would provide sufficient time for these smaller companies, "enabling them to remain in the marketplace and ensuring healthy competition in this area.'

Response: EPA does not agree that a different change of status date should apply to large companies as compared to small companies. The available alternatives that pose lower risk than those subject to the status change are equally available to businesses of all sizes. Under SNAP, EPA has not used the "size" of the user as a basis for its listing decisions and the commenter provides no basis related to the scope and purpose of the SNAP program to do so in this instance. EPA's decision regarding the status change dates for new retail food refrigeration equipment and new vending machines was based on the technical challenges faced by businesses of all sizes in adopting new refrigerants successfully in these products.

Comment: Some commenters indicated that they believe additional time is needed for smaller companies, especially businesses in the standalone/self-contained retail food refrigeration end-use that manufacture custom-built equipment and produce hundreds of models. The commenters also indicated particular challenges and disadvantages for small businesses as compared to larger businesses.

Response: We note that transition timelines in the NPRM were based on the Agency's information concerning the availability of alternatives for businesses of all sizes and we did not provide separate change of status dates for different size businesses. We address these concerns further in the previous comment and response.

# (c) Suggestion Regarding Education and Training

Comment: CFESA points to the need for "proper education and safety training for a successful and safe transition away from current refrigerants to the flammable or scarce refrigerants EPA deems acceptable." Other commenters likewise stated training of factory employees and service technicians would be required, especially if hydrocarbon refrigerants were employed.

Response: Because CFESA and others reference flammable refrigerants, EPA believes this comment is particular to stand-alone equipment and vending machines, where certain flammable refrigerants are currently acceptable subject to use conditions. However, for these two end-uses, not all refrigerants listed as acceptable are flammable. Acceptable alternatives for stand-alone equipment and vending machines, such as R-448A, R-449A, R-450A and R-513A, are nonflammable and operate at similar characteristics to R-404A and HFC-134a. CFESA does not specify which refrigerants it considers scarce. Nonflammable R-744 refrigerant, for example, is in ample supply. While some other refrigerants have not been produced in large quantities to date, production is increasing as demand increases, including R-448A, R-449A, R-450A and R-513A. Honeywell indicates that R-450A is soon to be produced in commercial quantities, and EPA expects it, along with other HFC/ HFO blends, will be available by the change of status dates of 2019 and 2020 for vending machines and stand-alone equipment. With respect to technician training, EPA agrees proper education and training is valuable, and we note that there are already many manufacturers and suppliers who have been conducting such training. For example, Shecco notes that "The GUIDE North America 2013 84 report has identified at least 165 [Heating, Ventilation, Air Conditioning, and Refrigeration] HVAC&R System & Component Manufacturers, and Engineering Contractors in the United States working with natural refrigerants already today. In reality we have a

reason to believe that this number is much higher." Coke noted that it has developed and trained a servicing network as it introduced R–744 equipment. Included in the docket to this rule is *Hydrocarbon Refrigerants—A Study Guide for Service Technicians*, published by the Refrigeration Service Engineers Society (RSES), that could be used for those wishing to service new stand-alone units and new vending machines using R–290, R–441A or R–600a.

The HFC/HFO blend alternatives, identified above, are nonflammable and operate at similar characteristics to those subject to the status change and therefore technicians should require only minimal extra training to use them. Because different change of status dates apply for the different refrigeration enduses technicians will have an opportunity to stagger training relevant for the different end-uses and they can build their skills across those end-uses over time.

## 7. Energy Efficiency Considerations

DOE has promulgated, in separate rulemakings and under separate authority, energy conservation standards for several types of equipment, including products that are affected by this rule. See section V.C.1.b for information regarding DOE energy conservation standards that are applicable to the equipment addressed in this rule. New equipment subject to this rule would need to meet the DOE requirements and the requirements of the status change by the dates established in these rules.85 We note that for each of these end-uses, there are many compliant models already commercially available that do not use the refrigerants subject to a change of status. Furthermore, for all the equipment subject to today's rule, there are examples, highlighted below, that show the energy efficiency using alternative refrigerants not subject to a change in status can be at least as good as, and often better than, the energy

efficiency of equipment using refrigerants whose status will change to unacceptable.

We note that we do not have a practice in the SNAP program of including energy efficiency in the overall risk analysis. We do, however, consider issues such as technical needs for energy efficiency (e.g., to meet DOE standards) in determining whether alternatives are "available." EPA recognizes that the energy efficiency of particular models of equipment is a significant factor when choosing equipment. We also recognize that the energy efficiency of any given piece of equipment is in part affected by the choice of refrigerant and the particular thermodynamic and thermophysical properties that refrigerant possesses. Although we cannot know what energy efficiency will be achieved in future products using a specific acceptable refrigerant, we can point to both actual equipment and testing results that show promise and often better results than the equipment using the refrigerants that we are finding unacceptable. (EPA-HQ-OAR-2014-0198-0134, EPA-HQ-OAR-2014-0198-0184, EPA-HQ-OAR-2014-0198–0077). We recognize that, while theoretical efficiency of any given Rankine cycle is not dependent on the refrigerant used, the refrigerant, the design of the equipment, and other factors will affect the actual energy efficiency achieved.

The efficiency can change based on the refrigerant chosen and there are various metrics, such as Total Equivalent Warming Impact (TEWI) and Life Cycle Climate Performance (LCCP), that account for climate effects of both emissions of the refrigerant and the possible emissions of greenhouse gases, primarily carbon dioxide, from the source of power to operate equipment. Quantification of the portions of TEWI/ LCCP from the refrigerant and energy use can only be done using broad assumptions that would not be applicable to all users of the myriad equipment models that are affected by today's rule. As noted in section V.C.1.b, energy conservation standards set by the DOE apply to some of the equipment covered by today's rule (e.g., stand-alone equipment, vending machines). If manufacturers were to offer equipment that meets, but does not exceed, that standard (or any other standard, such as ENERGY STAR®), then the indirect emissions from energy use would be the same regardless of which refrigerant were used. In that case, the refrigerant emissions would be the only factor that would decide which system has a lower TEWI or LCCP. Manufacturers that wish to exceed

<sup>84</sup> Shecco, 2013a: GUIDE 2013: Natural Refrigerants—Market Growth for North America, publication.shecco.com/publications/view/6

 $<sup>^{\</sup>rm 85}\, \rm Refrigeration$  equipment in the applicable covered equipment class would still be subject to DOE's standards, regardless of the refrigerant that the equipment uses. If a manufacturer believes that its design is subjected to undue hardship by a regulatory standard prescribed by DOE (in contrast to one that is statutorily prescribed by Congress), the manufacturer may petition DOE's Office of Hearing and Appeals (OHA) for exception relief or exemption from the standard pursuant to OHA's authority under section 504 of the DOE Organization Act (42 U.S.C. 7194), as implemented at subpart B of 10 CFR part 1003. OHA has the authority to grant regulatory relief from a standard promulgated by DOE on a case-by-case basis if it determines that a manufacturer has demonstrated that meeting the standard would cause hardship, inequity, or unfair distribution of burdens.

energy efficiency requirements may do so with any acceptable refrigerant they choose. Although some refrigerants will in the future be listed as unacceptable as determined in this final action, that does not directly affect the theoretical energy efficiency possible. As noted below, the results to date for actual equipment using acceptable alternatives do not show any significant decline in energy efficiency and often show the reverse. (EPA-HQ-OAR-2014-0198-0134, EPA-HQ-OAR-2014-0198-0184, EPA-HQ-OAR-2014-0198-0077). While various sources of data on energy efficiency results from testing acceptable refrigerants show varying results, we believe that with new designs to use these refrigerants, any lower energy efficiency results can be overcome and likewise existing energy efficiency levels can be improved.

Throughout the history of the SNAP program, EPA has seen the energy efficiency of refrigeration and airconditioning equipment increase, despite changing refrigerant options. In some cases, this was because new chemicals were developed that possessed unique properties that allowed high energy efficiency levels to be obtained. In many cases, technological improvement and optimization of equipment designs and controls has increased energy efficiency. Although today's rule lists some refrigerants as unacceptable, we do not believe it will have a detrimental effect on this trend in increased energy efficiency. In fact, there are multiple case studies available that highlight the energy efficiency gains achieved by some of the low-GWP refrigerants, such as R-744, which remains acceptable for the refrigeration end-uses addressed in this rule, and R-290 and R-600a, which remain acceptable subject to use conditions for new stand-alone equipment and new vending machines. (EPA-HQ-OAR-2014-0198-0134, Refrigeration and Air Conditioning Magazine, 2015).86 As part of our review of whether alternatives are "available," we determined that equipment has been designed for and is capable of meeting existing requirements such as the DOE energy conservation standards. Below we highlight the energy efficiency gains that have been reported for the commercial refrigeration end-uses and end-use categories affected by today's

Theoretical and prototype testing show similarly good energy efficiency

results. For instance, in supermarket refrigeration, a theoretical analysis (Emerson Climate Technologies, 2014) examined the energy use of R-407A and R-410A, both of which are on the list of acceptable substitutes, against that of R–404A, which is listed as unacceptable in new supermarket systems as of January 1, 2017. Although this analysis found that both blends would see a 3.6% to 6.7% drop in efficiency in the low-temperature part of the store (e.g., frozen food, ice cream), they would achieve a 4.3% to 13.3% increase in the medium-temperature part of the store (e.g., meat, dairy products, chilled prepared food). Given that supermarkets have significantly larger use of mediumtemperature equipment, the net effect would be for the equipment using those alternatives to use less energy than equipment currently designed to use R-404A. We have pointed out in Section V.C.2 above that R–407A in particular is widely used and we might expect it to be used in a large share of supermarkets after the change of status date. This analysis showed similar increases in energy efficiency of new supermarket and stand-alone equipment using a variety of low-GWP refrigerants as compared with equipment currently using R-404A.

The analysis also showed a slightly higher energy consumption by standalone equipment designed to use other alternatives as compared with one designed to use R-404A. One user of stand-alone equipment did not provide any specific results, but stated that "HC freezers are significantly more energyefficient." (Ben and Jerry's, 2014). True recently displayed several stand-alone units using R-290 refrigerant that were reported to be 15% more efficient than similar equipment using HFC-134a and R-404A.87 Similar results were seen by DuPont, who found that R-449A reduced energy usage when used in a display case connected to a remote condensing unit. They found that the energy consumption using this refrigerant was 2% to 3% less than R-404A in low-temperature tests and 8% to 12% less in medium-temperature tests. (EPA-HQ-OAR-2014-0198-0077).

Similar results are being seen with vending machines. As noted in the NPRM, one purchaser of vending machines indicated that while introducing over one million units using R-744, they have increased the energy efficiency of their cooling equipment

over 40% since 2000, at which time such equipment was exclusively using HFC–134a (Coca-Cola, 2014). More recently, it was reported that 78% of Coca Cola's models (vending machines and stand-alone cases) perform more efficiently than HFC units. (Refrigeration and Air Conditioning Magazine, 2015). Furthermore, it has been reported that PepsiCo has placed nearly one million hydrocarbon vending machines on the market and that these use 20% less energy than ENERGY STAR requirements.

As new products are designed to use particular refrigerants, manufacturers have the opportunity to change designs to take advantage of a given refrigerant's characteristics. The redesign and development phase is also an opportunity to improve other components that will affect the overall efficiency of the equipment, such as the use of more efficient motors and compressors, improved heat exchangers, better controls, improved insulation (e.g., on display cases) and sealing (for products with doors), more efficient lighting, etc. These opportunities and the examples provided are indicative that when redesigning equipment for a new refrigerant, energy efficiency is often improved. Multiple companies have reported such gains in the equipment covered by today's rule, for instance with R-407A or R-744 in supermarket systems, with HFC/HFO blends in remote condensing units, and with hydrocarbons and R-744 in standalone equipment and vending machines

## D. Foam Blowing Agents

#### 1. Background

Foams are plastics (such as PU or polystyrene) that are manufactured using blowing agents to create bubbles or cells in the material's structure. The foam plastics manufacturing industries, the markets they serve and the blowing agents used are extremely varied. The range of uses includes building materials, appliance insulation, cushioning, furniture, packaging materials, containers, flotation devices, filler, sound proofing and shoe soles. Some foams are rigid with cells that still contain the foam blowing agent, which can contribute to the foam's ability to insulate. Other foams are open-celled, with the foam blowing agent escaping at the time the foam is blown, as for flexible foams.

A variety of foam blowing agents have been used for these applications. Historically, CFCs and HCFCs were typically used to blow foam given their favorable chemical properties. CFCs and HCFCs are controlled substances under

<sup>&</sup>lt;sup>86</sup> Refrigeration and Air Conditioning Magazine, 2015. "Coca Cola to narrowly miss HFC-free global refrigeration target" (www.racplus.com/news/cocacola-to-narrowly-miss-hfc-free-global-refrigerationtarget/8680290.article).

<sup>&</sup>lt;sup>87</sup> Shecco, 2013b. "HCs gaining market prominence in US—view from The NAFE Show— Part 1" February 18, 2013. This document is accessible at www.hydrocarbons21.com/news/ viewprintable/3891.

the Montreal Protocol and subject to regulation under the CAA including a phaseout of production and import under section 604 for CFCs and section 605(b)–(c) for HCFCs and use restrictions on HCFCs under section 605(a). The regulations implementing section 610 of the CAA include a ban on sale or distribution of foam products blown with class I and class II ODS: However, for foam products containing a class II ODS, the ban is subject to an exception for foam insulation products as defined at 40 CFR 82.62.

HCFCs, which have a longer phaseout period than CFCs since they are less potent ozone-depleting substances, have continued to be used to some extent as foam blowing agents. In addition, the SNAP program has found acceptable a variety of non-ODS blowing agents, including HFCs (e.g., HFC–134a, HFC– 245fa, HFC–365mfc), hydrocarbons, carbon dioxide, water, methylal, methyl formate, HFO–1234ze(E), HFO– 1336mzz(Z), and trans-1-chloro-3,3,3trifluoroprop-1-ene (Solstice 1233zd(E)).

Blowing agents are approved on an end-use basis. The SNAP program considers the following end-uses:

- Rigid PU (appliance foam) includes insulation foam in domestic refrigerators and freezers.
- Rigid PU (spray, commercial refrigeration, and sandwich panels) includes buoyancy foams, insulation for roofing, wall, pipes, metal doors, vending machines, coolers, and refrigerated transport vehicles.

- Rigid PU (slabstock and other) includes insulation for panels and pipes.
- Rigid PU and polyisocyanurate laminated boardstock includes insulation for roofing and walls.
- Flexible PU includes foam in furniture, bedding, chair cushions, and shoe soles.
- Integral skin PU includes car steering wheels, dashboards, and shoe soles.
- Polystyrene (extruded sheet) includes foam for packaging and buoyancy or flotation.
- Polystyrene (extruded boardstock and billet) includes insulation for roofing, walls, floors, and pipes.
- Polyolefin includes foam sheets and tubes.
- Phenolic insulation board and bunstock includes insulation for roofing and walls.
- 2. What is EPA finalizing for foam blowing agents?

For foam blowing end-uses, EPA proposed to change the status for several substitutes, as of January 1, 2017, as follows:

- HFC–134a and blends thereof as unacceptable for all end-uses;
- HFC-143a, HFC-245fa and HFC-365mfc and blends thereof; and the HFC blends Formacel B, and Formacel Z-6 as unacceptable in all foam blowing enduses where they were on the list of acceptable substitutes at the time of proposal, except for rigid PU spray foam; and

• The HFC blend Formacel TI as unacceptable in all foam blowing enduses where it was on the list of acceptable substitutes at the time of proposal.

After considering the comments received on the proposed rule, EPA is making several changes to what it proposed in this final action. First, EPA is creating narrowed use limits for HFC-134a and blends thereof, for HFC-365mfc and blends thereof, and HFC-245fa and blends thereof for all foam blowing end-uses except rigid PU spray foam. EPA is also creating narrowed use limits for certain HFC blends, including Formacel TI, Formacel Z-6, and Formacel B, for those end-uses that were on the list of acceptable substitutes at the time of proposal. For all these substitutes, the narrowed use limits would be for military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements. For all other uses in these identified end-uses, the status would change to unacceptable, with the exception of rigid PU spray foam, for which we are not taking final action in this rule. Second, we are establishing change of status dates that range from January 1, 2017, to January 1, 2021. And, further, for the uses subject to the narrowed use limits, the status would change to unacceptable as of January 1, 2022. The change of status determination for each end-use is summarized in the following table:

TABLE 8—CHANGE OF STATUS DECISIONS FOR FOAM BLOWING AGENTS

End-use	Substitutes	Decision*
Rigid Polyurethane: Appliance	HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* and unacceptable for all other uses as of January 1, 2020. Unacceptable for all uses as of January 1, 2022.
Rigid Polyurethane: Commercial Refrigeration and Sandwich Panels.	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* and unacceptable for all other uses as of <i>January 1, 2020</i> . Unacceptable for all uses as of January 1, 2022.
Rigid Polyurethane: Marine Flotation Foam	HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* and unacceptable for all other uses as of <i>January 1, 2020</i> . Unacceptable for all uses as of January 1, 2022.
Rigid Polyurethane: Slabstock and Other	HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* and unacceptable for all other uses as of <i>January 1, 2019</i> . Unacceptable for all uses as of January 1, 2022.

TABLE 8—CHANGE OF STATUS DECISIONS FOR FOAM BLOWING AGENTS—Continued

End-use	Substitutes	Decision *
Rigid Polyurethane and Polyisocyanurate Laminated Boardstock.	HFC-134a, HFC-245fa, HFC-365mfc and blends thereof.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* and unacceptable for all other uses as of <i>January 1, 2017.</i> Unacceptable for all uses as of January 1, 2022.
Flexible Polyurethane	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* and unacceptable for all other uses as of <i>January 1, 2017</i> . Unacceptable for all uses as of January 1, 2022.
Integral Skin Polyurethane	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* and unacceptable for all other uses as of <i>January 1, 2017.</i> Unacceptable for all uses as of January 1, 2022.
Polystyrene: Extruded Sheet	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* and unacceptable for all other uses as of <i>January 1, 2017.</i> Unacceptable for all uses as of January 1, 2022.
Polystyrene: Extruded Boardstock and Billet (XPS)	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, Formacel B, and Formacel Z-6.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications * and unacceptable for all other uses as of <i>January 1, 2021</i> . Unacceptable for all uses as of January 1, 2022.
Polyolefin	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* and unacceptable for all other uses as of <i>January 1, 2020</i> . Unacceptable for all uses as of January 1, 2022.
Phenolic Insulation Board and Bunstock	HFC-143a, HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof.	Acceptable subject to narrowed use limits for military or space- and aeronautics-related applications* and unacceptable for all other uses as of January 1, 2017. Unacceptable for all uses as of January 1, 2022.

<sup>\*</sup>Under the narrowed use limit, use is limited to military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.

(a) What other alternatives does EPA find pose lower overall risk to human health and the environment?

In the NPRM, EPA included a comparative analysis, end-use by enduse, of the substitutes for which EPA proposed to change the status and the other available alternatives. 79 FR at 46151 to 46154. Most of the other alternatives that EPA identified as having lower risk than those for which we proposed to change the status have zero ODP or have negligible impact on stratospheric ozone. One alternative that contains chlorine, trans-1-chloro-3,3,3trifluoroprop-1-ene (SolsticeTM 1233zd(E)), has an ODP of 0.00024 to 0.00034 and estimates of its maximum potential impact on the ozone layer indicate a statistically insignificant impact, comparable to that of other substitutes in the same end-uses that are

considered to be non-ozone-depleting. 88 89 For the uses on which we are taking final action, the substitutes remaining acceptable have significantly lower GWP than the substitutes for which we are changing the status, with GWPs ranging from zero (water, vacuum panels) to 124 (HFC–152a) as compared with GWPs ranging from 725 to approximately 1,500. The substitutes changing status and the substitutes remaining acceptable all can be used such that the recommended workplace

exposure limit for the substitute is not exceeded in the end-uses where they are listed as acceptable, and thus, toxicity risks are comparable.

Most of the substitutes that remain acceptable are not VOC (e.g., water) or are exempt from the definition of VOC under CAA regulations (see 40 CFR 51.100(s)) addressing the development of SIPs to attain and maintain the national ambient air quality standards. Examples of VOC-exempt blowing agents include acetone, CO<sub>2</sub>, ecomate, HFC-152a, HFO-1234ze(E), methyl formate, and Solstice 1233zd(E). Other acceptable foam blowing agents are VOC, including saturated light HCs, Exxsol blowing agents, and methylal. In the risk screens that EPA performs when we review a substitute, we consider VOC emissions impacts, taking into account the rate of blowing agent

<sup>&</sup>lt;sup>88</sup> Wang D., Olsen S., Wuebbles D. 2011.
"Preliminary Report: Analyses of tCFP's Potential Impact on Atmospheric Ozone." Department of Atmospheric Sciences. University of Illinois, Urbana. IL. September 26, 2011.

<sup>&</sup>lt;sup>89</sup> Patten and Wuebbles, 2010. "Atmospheric Lifetimes and Ozone Depletion Potentials of *trans*-1-chloro-3,3,3-trichloropropylene and *trans*-1,2-dichloroethylene in a three-dimensional model." *Atmos. Chem. Phys.*, 10, 10867–10874, 2010.

emissions of particular foam end-uses, estimated market size, and the presence of emission controls in manufacturing for different end-uses. Estimated emissions for these three substitutes is sufficiently low that we do not expect significant air quality impacts (ICF, 2014h). The manufacturer of HFO-1336mzz(Z) claims that this substitute has low photochemical reactivity and has petitioned EPA to exempt it from the definition of VOC for purposes of the development of SIPs to attain and maintain the national ambient air quality standards, but EPA has not yet acted on that petition. Given the large variety of alternatives that do not increase VOC emissions, and the estimated low impacts from those alternatives that are VOC, we believe that changing the status of certain HFC foam blowing agents through this action will not significantly increase environmental or health risks.

Some of the substitutes that remain acceptable are flammable, but the hazards of these flammable compounds can be adequately addressed in the process of meeting OSHA regulations and fire codes in all end-uses except certain rigid PU spray foam applications. Examples of acceptable flammable blowing agents are HFC—152a, ecomate, Exxsol blowing agents, methylal, methyl formate, and saturated

light hydrocarbons.

Although EPA has listed a number of flammable alternatives as acceptable for most foam end-uses, that is not the case for rigid PU spray foams. Some of the lower-GWP, flammable alternatives that are listed as acceptable in other foam blowing end-uses, such as C3-C6 hydrocarbons and methylal, are not acceptable for use in rigid PU spray foam. For rigid PU spray foam applications, flammability risks are of particular concern, because they are applied onsite, sometimes in proximity to hot, flammable substances such as tar. Flammability risks are more difficult to mitigate in rigid PU spray foam than in most other foam end-uses because, unlike in a factory setting, in many cases ventilation cannot be provided that removes flammable vapors and maintains them below the lower flammability limit, and it is not practical to make all electrical fixtures explosion proof when applying rigid PU spray foam in a residential building. There are three main types of rigid PU spray foam: High-pressure two-part spray foam systems, low-pressure twopart spray foam systems, and onecomponent foam sealants.

For rigid PU spray foam, we are not taking final action in this rule. We intend to conduct a more extensive

comparative risk analysis of the substitutes available before taking final action. Thus, the substitutes currently listed as acceptable for spray foam are not affected by this rule but may be the subject of future rulemaking.

For more information on the environmental and health properties of the different foam blowing agents, please see the proposed rule at 79 FR 46151 to 46154 and a technical support document that provides additional **Federal Register** citations (EPA, 2015d) in the docket.

### (b) When will the status change?

For foam blowing agents, the time at which the status will change varies by end-use.

For the flexible PU, polystyrene extruded sheet, and phenolic insulation board and bunstock end-uses, many users have already transitioned from the foam blowing agents subject to the status change. No commenters suggested that, or provided information that would suggest, a later change of status date is necessary for these end-uses. Therefore, as proposed, we are establishing January 1, 2017 as the date of the status change for those end-uses.

For *PU* integral skin, the systems house BASF stated that they have had limited success thus far with HFO blowing agents in this end-use and would require at least two years to formulate and test a system and another six months for the new system to be commercialized and accepted by their customers in this end-use. However, this commenter did not provide specific details of the technical challenges they face nor why they believe two years, rather than a shorter time, is required for formulation and testing. Nor did the commenter explain why customer acceptance of the new system was related to technical feasibility that would require an additional six months beyond the time needed for formulation and testing. A period of two and a half years after issuance of the NPRM would be January 2017, rather than the July 1, 2017 suggested by the commenter. There are alternative foam blowing agents in addition to HFOs in this enduse that pose less risk overall to human health and the environment, such as HFC-152a and light saturated hydrocarbons. Therefore, as proposed, we are establishing January 1, 2017, as the date of the status change for PU integral skin foam.

For the rigid PU and polyisocyanurate laminated boardstock end-use, we did not receive any specific technical information nor any comments stating that a change of status date later than the proposed date of January 1, 2017,

was warranted. We received a general comment from EIA that the change of status date should be January 1, 2016, but they provided no information supporting this earlier date. We received a comment from one systems house, Huntsman, that provided specific technical information supporting a later change of status date for other PU enduses, but not PU and polyisocyanurate laminated boardstock. Another systems house, Dow Chemical, specifically mentioned that polyisocyanurate boardstock has previously safely transitioned to use of hydrocarbons. Therefore, as proposed, we are establishing January 1, 2017 as the date of the status change for PU and polyisocyanurate laminated boardstock.

For all other foam blowing end-uses for which we are taking final action, we received comments identifying technical challenges that mean other alternatives would not be available until a later date than January 1, 2017. Systems houses and appliance manufacturers also mentioned the need for third-party testing for end-uses such as extruded polystyrene boardstock and billet, rigid PU appliance, and rigid PU commercial refrigeration and sandwich panels. Systems houses and DuPont, a manufacturer of foam blowing agents, also were concerned with the supply of lower-GWP foam blowing agents, especially supply of HFOs (HFO-1234ze(E) and HFO-1336mzz(Z)) and *trans*-1-chloro-3,3,3-trifluoroprop-1-ene, and indicated this was a constraint that prevents transitioning away from higher GWP HFCs by January 1, 2017. EPA agrees that there is validity to these concerns, as discussed further below for each end-use.

For rigid PU slabstock, a systems house (Huntsman) commented they need additional time for testing and suggested a change of status date of January 1, 2019. Huntsman gave three specific reasons for why there should be a later change of status date than January 1, 2017 for this end-use: They believe it will take more than two years to develop products with alternatives, including third-party certification; they believe the long-term performance of HFO foams is not widely proven; and they believe there is insufficient supply and competition in the market for HFOs. Huntsman mentioned specific technical challenges, such as testing the compatibility and stability of the blowing agents with the polyol blends (i.e., other components needed in the foam formulation) and difficulties with stability of the catalysts when used with HFO blowing agents. They also stated that extended testing of more than six months was required to test strength,

thermal insulation capability and dimensional stability of the foam, including aging testing. Huntsman also mentioned testing the fire properties of the foams with different foam blowing agents as well as optimization of the blends. Huntsman stated that these steps required one to one and a half years initial development by the systems house that would then be followed by trials and custom modification at their customers facilities using their specific equipment and claimed that would require one to two years in addition. Considering the technical constraints described by the systems house such as the need to research different catalysts and the lower stability of some alternative foam blowing agents, we agree that it is reasonable to expect it would take three and a half years after this rule is final for alternatives to be available for this end-use. Therefore, we are establishing a change of status date of January 1, 2019, for rigid PU slabstock.

For rigid PU appliance foam, one systems house, BASF, commented that it took five years for them to assist the appliance manufacturer Whirlpool in its conversion from an HFC-blown foam to an HFO-blown foam, excluding flammability certification testing. While the Agency recognizes that as industry builds experience with new blowing agents, future transitions may be quicker because of the knowledge gained from earlier transitions, the Agency also understands that it may not be possible by 2017 to complete a full transition to alternative blowing agents for all appliance manufacturers, particularly if appliance manufacturers are maintaining or improving the thermal insulating value of the foam to meet DOE energy conservation standards. Appliance manufacturers and BASF have described the difficulty and time needed to overcome technical difficulties when using alternative blowing agents, particularly olefins such as trans-1-chloro-3,3,3-trifluoroprop-1ene or HFOs, that result in cracking, thinning of the foam, and irreparable field failures of the equipment. Appliance manufacturers and systems house Huntsman also mentioned the need for energy efficiency testing and third-party certification of equipment and claimed that would require at least one and a half to two years after the system house's development of foam formulations. However, the time required for ensuring adequate performance and third-party testing warrants a date as late as January 1, 2020. In addition to technical constraints, we also considered that

there is unlikely to be a sufficient supply of alternatives before January 1, 2017, for appliance foam; the supply is likely to increase once a commercial plant for HFO-1336mzz(Z) opens (currently scheduled to open in 2017). We considered the supply constraints mentioned by both systems houses and chemical producers (until 2017), technical constraints with alternative foam blowing agents that could result in failed appliances with insufficient research (requiring one to two years), and the need for third-party certification of each model (requiring one and a half to two years), and we agree that it is reasonable to expect it would take until 2020 for alternatives to be available for this end-use. We are establishing a change of status date of January 1, 2020, for appliance foam which allows sufficient time to work out these technical issues and to ensure a sufficient supply of various alternatives.

For rigid PU commercial refrigeration and sandwich panels, equipment manufacturers and systems houses such as Huntsman, Dow and BASF mentioned similar issues to those raised for appliance foam. Huntsman mentioned technical challenges in developing new formulations for PU insulation foam, such as testing the compatibility and stability of the blowing agents with the polyol blends (i.e., other components needed in the foam formulation) and difficulties with stability of the catalysts when used with HFO blowing agents. They also stated that extended testing of more than six months was required to test strength, thermal insulation capability and dimensional stability of the foam, including aging testing. Huntsman also mentioned the need for testing fire properties of foams with different foam blowing agents and optimization of the blends. Huntsman stated that these steps required one to one and a half years initial development by the systems house in a process involving iterative testing. Huntsman specifically mentioned steps such as developing new foam formulations (one to one and a half years), trials at the customers' plants (half to one year), third-party certification by UL, Intertek or Factory Mutual (one to one and a half years), and implementation of engineering changes at the customers' facilities (half to one year). We also considered that based on the information and comments we have received, there is unlikely to be a sufficient supply of alternatives for this end-use before January 1, 2017, as discussed above for appliance foam. The Laboratory Products Association, whose members manufacture very low

temperature freezers such as those used in the pharmaceutical industry, mentioned that some laboratory products using alternative foam blowing agents are medical devices listed by FDA, which would require re-approval after changing the blowing agent. Representatives of this application suggested coordinating with timelines of EU regulations (2022), without describing specifically why more time might be required for very low temperature freezers than for foam blowing agents in other commercial refrigeration equipment which also require third-party review. It is reasonable to expect that the timeframe required for commercial refrigeration foam and sandwich panels is comparable to that for appliance foam, requiring until 2017 for sufficient supply, and then another three years for development and testing of formulations and third-party testing of the resulting equipment or panels. We are establishing a status change date of January 1, 2020, for commercial refrigeration and sandwich panel foams, based on the time needed to resolve technical issues and on supply of alternative foam blowing agents.

For PU marine flotation foam, we received a comment from BASF indicating that systems houses will require at least a year for technical development, a year for certification testing to U.S. Coast Guard standards, a year for testing of the stability of the foam product, as well as one to two years for customer approval, given the large number of customers for this type of foam. BASF expected issues similar to those for appliance foam, such as dimensional stability and cracking, because injecting flotation foam is a similar process and uses similar polymers in the foam formulation. BASF asked that EPA clarify whether marine flotation foam fits under spray foam and whether this application is "exempted" or instead must transition to alternatives. EPA consulted with the U.S. Coast Guard regarding their certification process and the necessary time for manufacturers to test and certify that they meet the requirements at 33 CFR part 183 (Boats and Associated Equipment), Subparts F (Flotation Requirements for Inboard Boats, Inboard/Outdrive Boats, and Airboats), G (Flotation Requirements for Outboard Boats Rated for Engines of More than 2 Horsepower), and H (Flotation Requirements for Outboard Boats Rated for Engines of 2 Horsepower or Less), which require all manufacturers of monohull recreational boats less than twenty feet in length

(except sailboats, canoes, kayaks, inflatable boats, submersibles, surface effect vessels, amphibious vessels, and race boats) to provide sufficient flotation foam within the boat to ensure that the boat will not sink if the boat swamps or capsizes. This requirement allows the occupants to hold onto the boat until they can be rescued. We also met with representatives from the marine industry and heard directly from them about the necessary steps for transition. After considering the various steps needed to complete the transition, we conclude that the need for the systems houses to perfect formulations that perform similar or better than what is being used today will take additional time beyond what the Agency considered. In particular, in order to research and test foam formulations sufficiently to avoid issues with dimensional stability and field failures, and to ensure safety of the flotation foam and boats built with it, we expect it would take at least another two and a half to three years beyond the proposed date of January 1, 2017. Thus, we are establishing January 1, 2020 as the change of status date for marine flotation foam. We do not believe there is sufficient information at this time to support a change of status date later than January 1, 2020. However, given the concern for safety associated with marine floatation foam, we will monitor the situation carefully and consult with the U.S. Coast Guard. Given that under 33 CFR 183 manufacturers are required to certify to the U.S. Coast Guard that their boats have sufficient flotation to meet the regulations, EPA recognizes that the U.S. Coast Guard may be able to provide information concerning certification with the alternatives. As January 2020 approaches, we will continue to consult with the U.S. Coast Guard and consider whether it is appropriate to adjust the change in status date or to otherwise modify the SNAP listing to address any uses for which there may be technical challenges beyond January 1, 2020. We are listing this use separately from spray foam due to differences in the manner in which the foam is dispensed which make this use more similar to appliance foam and commercial refrigeration foam than spray foam. Our understanding is that flotation foam is typically injected rather than sprayed.

For polyolefin, there are niche applications and specialized plants that may have particular difficulty in transitioning away from HFC-134a because of the time required to build a pilot plant to work with products using a new gaseous blowing agent and to

retrofit current facilities to work with an alternative blowing agent. One manufacturer, Pregis, stated that they must upgrade facilities if they are to safely adopt flammable blowing agents when they have been using a nonflammable agent in the past. EPA recognizes that such changes to a facility may take several years. Considering the heightened challenges with these specialized facilities, we are establishing a change of status date of January 1, 2020, for polyolefin.

For XPS, manufacturers of XPS raised concerns about the energy efficiency of the foam using alternative agents, the extensive testing required, third-party certification, and the lack of alternatives and recommended that the status of HFC-134a change on January 1, 2021. Owens Corning mentioned specific steps such as laboratory studies to develop or test an alternative blowing agent, pilot tests, conversion of pilot testing to line production, quality assurance and quality control testing of the final product, and product certification. Dow and Owens Corning estimated it would take at least six years to convert multiple lines and multiple facilities from HFC-134a to an alternative. Owens Corning and Dow also cited an EPA memorandum supporting a transition away from HCFC-22 and HCFC-142b as foam blowing agents, which found that four years was necessary. Owens Corning raised concerns about the viability of CO<sub>2</sub> based on its impact on energy efficiency; the safety of hydrocarbons because of their flammability and the need to consider impacts of additional flame retardants on the foam; and the commercial availability of HFO-1234ze(E) and its technical viability. Dow stated that of the acceptable alternatives that EPA mentioned in the NPRM, only HFO-1234ze(E) has sufficiently low thermal conductivity and low permeability to meet industry standards (e.g., ASTM C 578). We agree that additional time is required to test and improve the quality of XPS manufactured using alternative foam blowing agents to ensure that it meets or improves upon thermal insulation requirements and passes third-party certification testing; it is reasonable to expect that at least five years is likely to be required for all steps to transition away from HFC-134a, given the status of current efforts to adopt lower-GWP alternatives for XPS. Members of the Extruded Polystyrene Association (XPSA) have stated that with XPS, it is not always possible to increase the thickness of the foam to maintain thermal insulation requirements,

because other construction materials (e.g., boards) may limit the thickness of boardstock foam. Thus, if alternative foam blowing agents did not produce foam meeting thermal insulation requirements, the transition in this enduse might not reduce climate effects as intended. Given the technical constraints, the need for third-party certification testing, and building code requirements for energy efficiency that may limit the available blowing agents, we are establishing a change of status date of January 1, 2021, for XPS. EPA notes that there is now a plant producing HFO-1234ze(E) in commercial quantities (Honeywell, 2015) and thus we do not believe that supply will limit the availability of alternatives.

## (c) Military and Space- and Aeronautics-Related Applications

We proposed to create a narrowed use limit exception to the unacceptable listing for military and space, and aeronautics uses that would allow continued use of HFC and HFC blend foam blowing agents through December 31, 2021. These blowing agents were proposed to be unacceptable for military or space- and aeronautics-related applications as of January 1, 2022. For the reasons discussed in the proposed rule, we are finalizing these provisions

as proposed.

ÉPA received comments from DoD and NASA supporting EPA's proposed narrowed use limit, and suggesting that this additional time is needed to identify, test and qualify substitutes for certain specialty applications. Boeing commented that the DoD and NASA need adequate time to develop, test and qualify an acceptable substitute for HFC-245fa, which is used in many foams they rely on for density foam insulation for a number of space and defense applications (e.g., rockets). Boeing did not identify any specific technical challenges but raised a general concern that, based on its experience with developing substitutes for foam blowing agents and the normal course of time to develop and qualify a substitute, it will take until 2027 to fully test and qualify a substitute. We do not believe there is sufficient information at this time to support a change of status date later than January 1, 2022; however, as January 2022 approaches, we can consider whether it is appropriate to adjust the change in status date or to otherwise modify the SNAP listing to address any uses for which there may be technical challenges beyond January 1, 2022.

Users that wish to use one of the substitutes listed as acceptable, subject to narrowed use limits, in a military or space- and aeronautics-related application must make a reasonable effort to ascertain whether other substitutes or alternatives are technically feasible and, if not, to document such results. See 40 CFR 82.180(b)(3). Users are not required to report the results of their investigations to EPA, but must retain the documentation in their files for the purpose of demonstrating compliance.

Documentation should include descriptions of:

- Process or product in which the substitute is needed;
  - Substitutes examined and rejected;
- Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or
- Anticipated date other substitutes will be available and projected time for switching.
- (d) How will the requirements apply to exports and imports?

Since regulations establishing the SNAP program were promulgated in 1994, we have interpreted the unacceptability determinations in this sector to apply to blowing foam with the foam blowing agent and not to products made with foam (e.g., 65 FR 42653, 42656; July 11, 2000). That is, an unacceptable foam blowing agent may not be used in, imported into, or exported from the United States. However, products made overseas with unacceptable foam blowing agents may be imported. For example, commercial refrigerators containing appliance foam blown with an unacceptable blowing agent may be imported into the United States, though appliances manufactured in the United States may not be manufactured with foam blown by that same agent.

In the proposal, EPA took comment on a different interpretation of our regulations under which the unacceptability determination would apply to imported products containing closed cell foam that contain any of the blowing agents listed as unacceptable, as well as applying to the blowing agent itself. Public commenters stated that this was a significant departure from the Agency's previous interpretation and suggested that EPA needed to explain the basis for such a change. In addition, some commenters pointed out that the proposal only allowed 60 days before this change in interpretation would apply to HCFC-141b, which they viewed as insufficient time to adjust. EPA is not finalizing this change in its interpretation in this action; however, we plan to continue assessing the merits of this change and may provide further

- explanation and opportunity for comment in a subsequent rulemaking.
- 3. How is EPA responding to comments concerning foam blowing end-uses?(a) Timeline

Comment: EPA received comments from more than 500 commenters concerning the proposal of January 1, 2017, as the status change date for the foam blowing agents addressed in the proposed rule. EIA and Honeywell suggested an earlier date of January 1, 2016, for all or most foam end-uses. Most other commenters suggested later dates, varying from July 1, 2017, to January 1, 2025. Some commenters indicated that they are small companies and they believe additional time is needed beyond that in the NPRM to reduce cost pressures. Some commenters suggested different dates for specific uses and gave a number of reasons for which dates would be appropriate for those uses. General reasons given for the need for additional time include: Time needed for capital investments, for employee training, for re-formulating systems; for designing, purchasing, awaiting receipt of and converting equipment; for obtaining local permits for VOC emissions; for meeting company and external testing requirements (e.g., UL/Factory Mutual (FM) fire safety requirements, DOE energy conservation standards, building codes, R-value testing for aged foam), and if switching to a flammable foam blowing agent, facility engineering design and refurbishment. Several commenters stated that there are no "drop in" replacements, and that product research and development is an iterative process. Owens Corning cited EPA's previous recognition of time limitations in the conversion away from HCFC–142b to HFC–134a, including an EPA staff memorandum that estimated a four-year transition time period in the foam sector. Some commenters also suggested that EPA adopt the same dates for transition for foams as in the European Union's "F-gas" rule: 2020 for XPS and 2023 for other foam types. In addition, some commenters suggested that there is an insufficient supply of low-GWP foam blowing agents that will maintain energy efficiency and insulation value of foam. Huntsman stated that there will not be enough capacity and competition in the HFO foam blowing market by January 1, 2017, to meet the needs of the PU foam industry. DuPont commented that while multiple low GWP alternatives will be available for foam, they will not be broadly available in the proposed timeframe.

Response: EPA notes that in a number of foam blowing end-uses, the industry has already effectively transitioned away from HFCs and any additional transitions for these end-uses can be made by January 1, 2017. Further, we received no comments suggesting a later transition date is necessary specifically for these end-uses. We received comments suggesting that this change of status could be made by January 1, 2016, but in the unlikely event that there are any end users that have not already transitioned, we are concerned that this date may be too soon to finish adopting an alternative. Therefore, the final rule retains the proposed change of status date of January 1, 2017, for those uses (polystyrene extruded sheet, flexible polyurethane, and phenolic insulation board and bunstock). In addition, we received no comments specific to rigid PU and polyisocyanurate laminated boardstock that indicated there were challenges for this end-use that would prevent a transition to alternatives that pose lower overall risk to human health and the environment by January 1, 2017. EIA suggested that we set a status change date of January 1, 2016, for this end-use, but did not provide information supporting an earlier transition for this end-use. Therefore, we are retaining this date in the final rule for rigid PU and polyisocyanurate laminated boardstock.

EPA agrees that additional time is needed for other specific foam types and addresses the basis for establishing later change of status dates in the discussion of each end-use above. We appreciate and agree with commenters that note the importance of maintaining energy efficiency for appliances and buildings by ensuring there is adequate time to develop and deploy new formulations that meet or exceed existing thermal insulating values. Further, we recognize that third-party testing or witness testing will require additional time that may be outside the control of the companies manufacturing the foam. Some of this testing, such as fire safety testing for construction foams, could help reduce any potential flammability risks associated with the use of flammable foam blowing agents. Businesses of all sizes will be able to benefit from the later change of status dates in this final rule. We discuss comments specific to each end-use below in this section.

Comment: Huntsman, a systems house, commented they need additional time for testing alternatives in the PU slabstock end-use and suggested a change of status date of January 1, 2019. Huntsman mentioned specific technical challenges with reformulating these

foam products, such as testing the compatibility and stability of the blowing agents with the polyol blends (i.e., other components needed in the foam formulation). They also stated that extended testing of more than six months was required to test strength, thermal insulation capability and dimensional stability of the foam, including aging testing. Huntsman also mentioned testing the fire properties of the foams with different foam blowing agents as well as optimization of the blends. Huntsman stated that these steps required one to one and a half years initial development by the systems house, to be followed by trials and custom modification at their customers' facilities using their specific equipment that would require another one to two years. The commenter also raised concerns about whether sufficient supply of alternative foam blowing agents would be available by January 1, 2017, and mentioned that there is currently a single supplier of a key low GWP foam blowing agent, trans-1chloro-3,3,3-trifluoroprop-1-ene.

Response: Considering the technical constraints raised by the systems house, such as the need to research different catalysts and fire retardants and the lower stability of some alternative foam blowing agents, we agree that safer alternatives will not be available for this end-use for three to three and a half years. Therefore, we are establishing a change of status date of January 1, 2019 for PU slabstock foams.

Comment: Commenters suggested change of status dates for rigid PU appliance foam, ranging from July 1, 2017 to January 1, 2020. BASF suggested a transition date of July 1, 2017 for foam used in domestic refrigerators. In support of a July 1, 2017, change of status date, BASF indicated that HFO-containing foams are incompatible with common polymers used in household refrigerators and that it will take a minimum of six months to perform durability and field testing and possibly to change construction materials to resolve this known problem, as well as at least six months for testing for compliance with federal energy conservation standards and 12 more months for conversion at each customer's facility. BASF also stated that they had already developed commercially available systems using cyclopentane and HFOs, so they expected this transition to take less time than the five years that it took to assist the appliance manufacturer Whirlpool in its conversion from an HFC-blown foam to an HFO-blown foam, excluding flammability certification testing.

Solvay commented that technical questions about alternatives still remain, such as whether substitutes other than HFCs attack panel walls or appliance walls, which could compromise product integrity and safety, and whether other alternatives adhere properly to appliance and panel walls, or to walls and roofs, which is necessary to satisfy energy efficiency mandates. Huntsman mentioned the need for energy efficiency testing and third-party certification of equipment that would require at least one and a half to two years after the system house's development of foam formulations, which it estimated to take one to one and a half years. Huntsman suggested a change of status date of 2019 for PU appliance foam. The Association of Home Appliance Manufacturers (AHAM) raised concerns about the potential adverse impacts on appliance quality, performance, and longevity, as well as costs, of a transition by January 1, 2017, and stated that the easiest and cheapest transitions have been done, and will be done, first. AHAM suggested a change of status date of 2020 for appliance foam to allow for coordination with DOE energy conservation standards that could take effect in 2020 for household refrigerators and freezers. In addition, AHAM claimed a 2020 change of status date was necessary because of the extensive time required for testing and third-party certification of multiple models, and additional time needed to ensure proper development of new alternatives to avoid field failures of the equipment.

Response: We agree that it is important that appliance manufacturers are able to ensure the quality, performance, and useful lifetime of their equipment. Multiple commenters provided information and photographs demonstrating that improperly implemented alternative foam blowing agents can create defects in the appliances, such as cracking or improper adhesion to the appliance cabinet. BASF suggested that it would take closer to two and a half to three years to work out the technical issues since they have already developed commercially available systems using HFOs and hydrocarbons for other appliance manufacturers. Because of the time required for ensuring adequate performance and third-party testing, we believe that other alternatives will not be available for an industry-wide transition until January 1, 2020. In addition to technical constraints, we also considered that there is unlikely to be a sufficient supply of alternatives

before the change of status date we proposed—January 1, 2017 for appliance foam. The supply is likely to increase once a commercial plant for HFO–1336mzz(Z) opens (currently scheduled to open in 2017) and thus supply would not be a concern for a change of status date of January 1, 2020.

Comment: For rigid PU commercial refrigeration foams and sandwich panels, commenters suggested change of status dates ranging from July 1, 2018, to ten years after the rule is final. The majority of commenters suggested status change dates ranging from July 2018 to January 1, 2020. NAFEM and manufacturers of commercial refrigeration equipment such as Traulsen suggested a much later date of 2025 for all modifications required for commercial refrigeration equipment, including both foam blowing agents and refrigerant.

As an initial matter, Huntsman and DuPont mentioned the lack of sufficient supply of alternatives to allow all foam users to convert in 2017. In support of a later change of status date, equipment manufacturers and systems houses such as Huntsman, Dow and BASF mentioned similar technical issues to those for appliance foam, such as the compatibility and stability of the blowing agents with the polyol blends and dimensional stability of the blown foam. BASF specifically mentioned reactions between the new blowing agents and the catalysts in the foam that could cause the finished foam to shrink, as well as the need to develop a new set of flame retardants. Commenters also stated that extended testing of more than six months was required to test strength, thermal insulation capability and dimensional stability of the foam, including aging testing. Huntsman specifically mentioned steps such as developing new foam formulations (one to one and a half years), trials at the customers' plants (half to one year), third-party certification by UL, Intertek or Factory Mutual (one to one and a half years), and implantation of engineering changes at the customers' facilities (half to one year), with iterative testing often required. Unified Brands and NAFEM suggested that there are limitations to using methyl formate in commercial refrigeration foam that would not allow a transition by January 1, 2017, stating: "Methyl Formate is also environmentally friendly, but has had significant shrinkage issues once units have been placed in the field. This agent requires very specific foaming processes to be developed to ensure proper stability of the foam over time.'

Response: We agree that there are a number of technical challenges that will

require approximately four to five years for the industry as a whole to transition to alternatives, including stability of new formulations and difficulty with using existing catalysts with alternative foam blowing agents. We agree that there is unlikely to be a sufficient supply of alternatives for this end-use before the proposed change in status date January 1, 2017. However as discussed above for appliance foam, additional supply should be available in 2017 when a new manufacturing plant is scheduled to open and there should be a more than sufficient supply to meet a status change date of January 1, 2020.

The later dates of ten years after finalization of the rule or 2025 suggested by NAFEM and other OEMs, appear to be based on the assumption that stand-alone retail food refrigeration equipment would need to use propane or other flammable refrigerants and that changes would need to be made to building codes to support the adoption of these flammable refrigerants. However, as discussed above in section V.C on commercial refrigeration, there are other available refrigerants that are nonflammable. Moreover, the commenters did not make clear why, even assuming that alternative refrigerants would not be available until 2025, the insulation foam for such equipment cannot be made using safer alternatives well before 2025. Thus we do not believe that safe alternative foam blowing agents will not be available before 2025.

Comment: Honeywell stated that "the technical requirements [for flotation foam in boats] may be much simpler than other industries in which customers are already transitioning" and suggested that a transition date of January 1, 2016 might be achievable for this application. BASF commented that systems houses will require at least a year for technical development, a year for certification testing to U.S. Coast Guard standards, a year for testing of the stability of the foam product, as well as one to two years for customer approval, given the large number of customers for this type of foam. This commenter recommended that EPA set a change of status date no earlier than July 1, 2019. BASF expected issues seen with appliance foam also to exist with marine flotation foam, such as dimensional stability and cracking, because injecting flotation foam is a similar process and uses similar polymers in the foam formulation. Ninety-four letters from the marine industry comment that, according to their suppliers in the boating industry, a drop-in replacement for HFC-134a currently does not exist, and will not be readily available by

2017. EPA received comments from 436 boat manufacturers to the effect that the continued introduction of regulations on the boating industry disproportionately affects their small businesses because the cost of compliance with these standards is relatively equal across production scales. According to these comments, EPA's proposed timeline for "phasing out" HFC-134a will have highly negative consequences for all facets of the marine industry, but it will have the greatest impact on their small boats, small businesses, and middle class customers. EPA received 93 letters from the marine industry stating that the boating industry consists primarily of small businesses that would face severe impacts as a result of their limited financial resources and limited influence on markets and supply chains. The National Marine Manufacturers Association (NMMA) also commented that the NPRM date would present a financial and logistical hardship for many small boat builders. NMMA urged the EPA to provide an extension of the proposed timeline. Commenters from the marine industry suggested 2022 as a transition date and mentioned the lack of availability of feasible options and marine application's dependency upon chemical availability from the larger industry (e.g., HFC-134a for use in MVAC). These commenters also mentioned the need for testing to meet Coast Guard requirements at 33 CFR

Response: Regarding the supply of alternatives, we recognize that a plant that would produce HFO-1234ze(E) in commercial quantities has recently been built (Honeywell, 2015). Additionally, supply of HFC-134a should not be an issue as many other uses of that substitute will be ending in the next several years. We do not agree that the certification processes will require additional time beyond EPA's understanding at the time of the proposal. It is our understanding that HFOs can be used in this type of foam. However, as with appliance foams, we agree that systems houses will need time to perfect formulations that perform similar or better than what is being used today. In particular, issues with stability of the blown foam likely will require several years to work out, as discussed above for appliance foam. Considering this information, we are establishing January 1, 2020, as the change of status date for marine flotation foam.

Comment: DuPont stated that polyolefin plants typically are specialized plants for niche applications and that this end-use may have

particular difficulty in transitioning away from HFC-134a; DuPont suggested that EPA consult with manufacturers in this end-use on appropriate transition timing. One manufacturer, Pregis, stated that they must upgrade facilities if they are to safely adopt flammable blowing agents when they have been using a nonflammable agent in the past. They also suggested that EPA consider a change of status date of 2022 because of the time required to build a pilot plant to work with products using a new gaseous blowing agent (two years)which has yet to begin—and the time to retrofit current facilities to work with an alternative blowing agent (another two years).

Response: EPA recognizes that construction of a pilot plant and making the necessary changes to an existing facility could take approximately four years after this rule is final; however, it is not clear from Pregis's description that they will require six years or more. Considering the heightened challenges with these specialized facilities, we are establishing a change of status date of January 1, 2020, for polyolefin.

Comment: Manufacturers of XPS raised the energy efficiency of the foam using alternative agents as an issue, the extensive testing required, third-party certification, and the lack of alternatives as reasons for allowing until January 1, 2021 for a change of status. Owens Corning mentioned specific steps such as laboratory studies to develop or test an alternative blowing agent, pilot tests, conversion of pilot testing to line production, quality assurance and quality control testing of the final product, and product certification. Dow and Owens Corning estimated it would take at least six years to convert multiple lines and multiple facilities from HFC-134a to an alternative. Owens Corning and Dow also cited an EPA memorandum supporting a transition away from HCFC-22 and HCFC-142b as foam blowing agents, which found that four years was necessary. Owens Corning and XPSA commented that a more realistic status change date of 2021 would also be consistent with the proposed status change date for MVAC.

IP Moulding commented that it had tried to use CO<sub>2</sub> and water in its extruded polystyrene molding process in the past and found it did not create sufficient internal pressure for their product; they are further investigating this option with their polystyrene supplier. Mexichem commented that carbon dioxide may not be suitable for the XPS industry because of its high thermal conductivity (low insulation value) and processing difficulties. Owens Corning raised concerns about

the viability of CO<sub>2</sub> based on its impact on energy efficiency; the safety of hydrocarbons because of their flammability and the need also to consider impacts of additional flame retardants on the foam; and the commercial availability of HFO-1234ze(E) and its technical viability. Honeywell commented that CO2 is an option for XPS, and that Dow has commercialized other solutions to improve energy efficiency with CO<sub>2</sub> such as Dow's XENERGY technology, which, according to Dow's Web site, has up to 20% higher insulating properties than its STYROFOAM<sup>TM</sup> polystyrene product that uses HFC-134a. XPSA commented that one of the alternatives in the proposed regulations (HFO– 1234ze(E)) is commercially suboptimized, and thus, XPSA's members have not conducted testing to confirm that they can be used to produce products that provide comparable thermal efficiency or if there are any other issues that would make them an unacceptable alternative to HFC-134a. Dow stated that of the acceptable alternatives that EPA mentioned in the NPRM, only HFO-1234ze(E) has sufficiently low thermal conductivity and low permeability to meet industry standards (e.g., ASTM C 578).

Response: Regarding concerns about the supply of HFO-1234ze(E), EPA notes that since the third quarter of 2014, there has been a plant producing HFO-1234ze(E) in commercial quantities (Honeywell, 2015), and a smaller plant was providing lots upon request before this. Based on the information we received, we agree that additional time is required to test and improve the quality of XPS produced using alternative foam blowing agents and for third-party certification testing. Thus, it is reasonable to expect up to three years to complete formulation development and to conduct pilot testing, an additional two years to convert the existing plant and test the quality of the final product (with some overlap with the pilot testing period), and a year for certification testing. The total time needed is five and a half to six years. Therefore, we are establishing a change of status date of January 1, 2021, for the XPS end-use.

EPA agrees that additional work with CO<sub>2</sub> as the blowing agent for XPS may be required to provide a better performing foam. Available information indicates CO<sub>2</sub> has a higher thermal conductivity than HFC–134a or HFO–1234ze(E), and thus, would be expected to provide lower insulation value in the absence of major changes to the foam formulation. The information on Dow's Web site that Honeywell references,

although encouraging, is not sufficient to determine if  $CO_2$  is the sole blowing agent and if the XENERGY technology that Honeywell mentions may be used in all the applications where XPS blown with HFC-134a is currently used. The information provided by Honeywell implies that with additional work, XPS blown with CO<sub>2</sub> could be more broadly available and could result in XPS with better foam insulation properties than current XPS foam using HFC-134a. Regarding comments suggesting that a status change date of January 2021 is appropriate because it would be consistent with the status change date of MY 2021 for MVAC, we first note that the transition for MVAC is required as of MY 2021, which will be completed in calendar year 2020. More importantly, the change of status date for each enduse is based on an evaluation of when alternatives will be available within that specific end-use. The change of status date for MVAC is not relevant for purposes of determining when safer alternatives will be available for the XPS foam blowing end-use.

### (b) Foam Blowing Agents Changing Status and Other Alternatives

Comment: Some commenters, including commercial refrigeration equipment manufacturers and environmental groups, support EPA's proposal to find higher GWP HFCs unacceptable in all foam blowing enduses. Others, including manufacturers of household appliances and AHAM, advised EPA to reconsider the proposal, stating that it unnecessarily accelerates the transition away from widely used chemicals that still have "significant beneficial uses" in the United States (e.g., HFC–245fa in appliance foam). Solvay stated that the entire foam blowing sector should have been excluded from the proposal to change the status of certain HFCs.

Response: We disagree that this action "unnecessarily accelerates" the transition away from chemicals that have significant beneficial use. EPA applied the SNAP criteria when making determinations on what to include in the proposed rule. For the reasons provided above and in the proposed rule, we have determined in most foam blowing end-uses that there are other alternatives that pose less risk than those for which we are changing the status.

Comment: DuPont commented that the category of Rigid Spray Polyurethane foam incorporates several product sub-categories, including high pressure spray foam and low pressure spray foam, each requiring different foam expansion agent characteristics

and therefore different alternatives and different testing requirements. DuPont and the Center for the Polyurethanes Industry recommended that EPA create separate SNAP categories for highpressure spray foam systems, lowpressure foam systems, and one component spray foam sealants to allow appropriate change of status dates for each. DuPont suggested that EPA not change the status of HFC-134a in lowpressure two-part spray foam and in one-component foam sealants, because these applications require a gaseous foam blowing agent, and not a liquid agent such as HFC-245fa or HFC-365mfc.

Response: EPA recognizes that a gaseous foam blowing agent is required for these uses, unlike for high-pressure two-part spray foam systems, and thus, there is reason to differentiate between low-pressure two-part spray foam systems, one-component foam sealants, and high-pressure two-part spray foam. We intend to conduct a more extensive comparative risk analysis of the substitutes available in each of these spray foam categories before taking final action. Thus, the substitutes currently listed as acceptable for spray foam are not affected by this rule but may be the subject of future rulemaking.

Comment: Unified Brands and NAFEM commented that water-based blowing agents are environmentally friendly, but suffer from poorer insulation performance and vulnerability towards processing temperatures that would consequently require improved control of fixture temperatures. Thermo Fisher commented that water-blown foam could lead to equipment with reduced energy efficiency and negative environmental impact because of its poor insulating properties.

Response: It is EPA's understanding that water-blown foams offer lower energy efficiency than foams blown with a number of other blowing agents. This is not a barrier to use for foam applications that do not require thermal insulation or for which increased thickness of the foam is not an issue. However, thickness of the foam is likely to be an issue for foams where the dimensions cannot be increased, such as foams used in refrigerated transport or sometimes in construction foams such as XPS or PU spray foam.

Comment: Mexichem commented that using hydrocarbons as a blowing agent may result in less thermally efficient XPS (as compared to use of HFC-134a). Unified Brands and NAFEM suggested there are complications with use of hydrocarbons in commercial refrigeration foam, and that "Pentane

based blowing agents are strong candidates due to their insulation performance, but require all foam fixtures and processes to be redeveloped" due to flammability. Dow stated that that HC technology is well understood, and it has been broadly deemed inappropriate for use as a blowing agent for XPS and SPF building and construction products in the United States. Dow also stated that HCs have been proactively adopted for use with polyisocyanurate foams, where they may be used safely. EIA commented that hydrocarbons have been used as blowing agents in Europe since 1992, including in insulation foams.

Response: It is EPA's understanding that hydrocarbons such as pentane and isopentane have better thermal conductivity than CO2, but not as good as that of HFCs or HFOs. This is not a barrier to use for foam applications that do not require thermal insulation or where increased thickness of the foam is acceptable. We also recognize that additional safeguards must be taken when using hydrocarbon foam blowing agents, such as improving ventilation, training staff, and explosion-proofing electrical fixtures. These steps can reasonably be taken in a manufacturing facility but are more difficult for installation in place, as with PU spray foam.

Comment: Honeywell commented that in many instances, customers are seeing benefits such as better performance, energy efficiency, nonflammability, and better product yields (less foam for the same performance) when using 1233zd(E) (trans-1-chloro-3,3,3-trifluoroprop-1ene). This commenter claimed that this foam blowing agent has been commercial in the United States in spray foam applications for more than a year, and in Japan, EU and China for a variety of foam applications, including appliance, panel and spray foam. Several users of trans-1-chloro-3,3,3trifluoroprop-1-ene mentioned its properties, such as improved compressive strength, lower density, better dimensional stability, and higher R-value (All-Weather Insulated Panels, West Development Group for spray foam, UTMC for commercial refrigeration foam in refrigerated

Response: Available information indicates that trans-1-chloro-3,3,3-trifluoroprop-1-ene has many performance characteristics, including improved insulation value, that should allow its adoption as a foam blowing agent in appliance foam, sandwich panels, and some spray foam applications.

(c) Environmental and Energy Impacts of Foam Blowing Agents

Comment: A number of commenters provided comments on the potential impact of the proposal on greenhouse gas emissions. AHAM state that they believe the proposed rule is unnecessary to protect the environment, because the use and potential emissions of high GWP HFC blowing agents for household refrigerators sold in the U.S. market are far less than what EPA estimated. DuPont comments that given that HFCs remain in these closed cell foams and provide valuable insulating properties, emissions of HFCs from foam production are roughly one-third of total HFC use in foams, or about 5% of total HFC emissions on a CO<sub>2</sub> equivalent basis. Two commenters in the foam blowing industry comment that EPA should consider the greenhouse gas emissions and energy savings over the lifetime of a product.

Response: Some commenters have suggested that because current HFC blowing agents, including HFC–134a in XPS, result in foams with energy efficiency that reduce overall GHG emissions, EPA should not change the status of HFC-134a, or at least should consider overall lifecycle climate impacts. While we do not consider energy efficiency as part of our overall risk analysis, we believe that other alternatives, such as olefin foam blowing agents, could improve energy efficiency even more than HFC-134a and other high GWP HFC blowing agents. Further, as explained below in our discussion of energy efficiency, listing higher GWP HFCs unacceptable likely would improve, rather than worsen, overall lifecycle GHG emissions. EPA recognizes that additional time is needed to ensure that the formulations provide equal or better thermal insulating value given the iterative process that can involve chemical manufacturers, system houses and end users. The change of status dates reflect the need to ensure that these technical challenges can be addressed.

Comment: Imperial Brown comments they cannot know if what is developed as an alternative will enable the resulting foam panels to meet DOE thickness requirements, because there is not a Class 1 polyurethane foam system on the market that utilizes a new blowing agent. Thermo-Kool comments that new foam formulations are not guaranteed to have insulating capabilities comparable to what is available today to satisfy DOE requirements. American Panel Corporation does not intend to use

pentanes in its foam blowing application, because the U.S. DOE has established new requirements that do not permit pentanes for walk-in panel manufacturers, as they would increase the panel thickness size. International Cold Storage, Crown Tonka, and ThermalRite Walk-Ins stated that lower R-Values will require additional insulation thickness to meet the energy regulation, thereby requiring expensive, complex, and costly modifications to new walk-in coolers and freezers that may sit side-by-side with identical existing equipment that offers the same degree of performance and protection.

Response: EPA recognizes that different foam blowing agents result in different insulation values. We note that some of the acceptable alternative foam blowing agents, such as HFO-1234ze(E), trans-1-chloro-3,3,3,-trifluoroprop-1ene, and HFO-1336mzz(Z), are expected to provide better insulation value than the HFC blowing agents listed as unacceptable in this action. EPA is not specifically aware of which, if any, of these alternatives has been tested by Factory Mutual (FM) and already qualifies as a "Class 1 polyurethane system." Other foam blowing agents are expected to have comparable or lower insulation value, such as CO<sub>2</sub>, ecomate and hydrocarbons. Given the variety of foam blowing agents available, we expect that foam products that need higher energy efficiency will have foam blowing agents available that will result in lowering the GHG emissions and energy savings over the lifetime of a product.

Comment: A number of commenters stated that they believed the proposed rule will result in increased energy consumption, potentially negating the overall net GHG emission reductions. One commenter, AMS, believes the effect of the proposed rule on energy consumption is a big unknown at this time. Structural Composites and Compsys, Inc., stated that the efficiency and reduced manufacturing impact of their PRISMA technology offsets the climate impacts from the small amount of HFC-134a used in their foam. ACMA stated that composite panels made using foam blown with HFC-134a for refrigerated transport dramatically reduce fuel usage, and therefore, exhaust emissions, because the panels are so lightweight. They suggested, therefore, that the environmental benefits of a transition away from HFC-134a are outweighed by emissions reductions achieved through lighter, HFC-134a blown panels. Honeywell provided information on the relative energy efficiency, in terms of lambda values, for CO<sub>2</sub>, HFC-134a and HFO-

1234ze(E), and stated that HFO-1234ze(E)'s energy efficiency properties are comparable and in some instances better than HFC-134a for XPS. Mexichem claimed that HFO-1234ze(E) is not nearly as energy efficient as HFC-134a and stated that it is not clear that XPS produced with HFO-1234ze(E) will provide the same thermal efficiency as achieved with HFC-134a, because HFO-1234ze(E) is not available for the industry to begin product testing. DuPont comments that the emerging low GWP HFO foam alternatives can deliver marked energy efficiency improvements over current alternatives when they become commercially available.

Response: EPA notes that some of the acceptable alternative foam blowing agents, such as HFO-1234ze(E), trans-1chloro-3,3,3,-trifluoroprop-1-ene, and HFO-1336mzz(Z), can provide better insulation value than the HFC blowing agents we are listing as unacceptable. Contrary to Mexichem's unsupported assertion that HFO-1234ze(E) is not nearly as energy efficient as HFC-134a, another commenter provided information showing that HFC-134a has a lambda (thermal conductivity) value of 29 to 30, while HFO-1234ze(E) has a lambda value of 27 to 30 that shows better insulation (Honeywell, 2014b). Other foam blowing agents have comparable or lower insulation value, such as CO<sub>2</sub> ecomate and hydrocarbons. Given that there are multiple foam blowing agents available that have lower thermal conductivity and better insulation value in each of the end-uses where we are changing the status of one or more foam-blowing agent, we expect that foam products that require higher energy efficiency will be able to use foam blowing agents that will result in lowering the GHG emissions and energy savings over the lifetime of a product, rather than raising it. For example, home appliances that currently use HFC-245fa could use trans-1-chloro-3,3,3,-trifluoroprop-1-ene or HFO-1336mzz(Z) and thereby ensure they meet DOE energy conservation standards. Similarly, information from the supplier of HFO-1234ze(E) indicates that XPS would maintain or improve its energy efficiency if HFO-1234ze(E) were used instead of HFC-134a as the blowing agent. Manufacturers of alternative panels or composite materials have not provided information showing that use of an alternative blowing agent would adversely affect the weight of foam formulations and thereby reduce fuel efficiency.

(d) Cost Impacts

Comment: Commenters express concern about the costs of the transition required by the proposal, including:

- capital costs;
- research, reformulation, and testing;
- technology and equipment;
- conversion, system re-design, and retrofit:
  - certification;
- costs for the recreational boating industry;
  - increasing cost of HFC–134a;
  - increases in costs to consumers;
  - market competitiveness impacts;
- reduction in new product development:
- retesting required due to lack of coordination with timing of requirements for DOE energy conservation standards;
  - economic impacts on branding:
  - cost savings; and
  - other general economic concerns.

Some commenters, such as Mexichem, Solvay, and AHAM, suggested that it was not necessary to change the status of HFC-134a and other HFC foam blowing agents or to require industry to incur the costs that these changes require. Other commenters, such as NMMA, NAFEM, XPSA, and their members, requested additional time for the change of status of HFC-134a and other HFC foam blowing agents in order to allow them to spread costs out over time and thus make costs of the transition more manageable. Imperial Brown suggested a later status change date to allow foam manufacturers to create sufficient supply, thereby alleviating a potential cost premium associated with scarcity of newer alternatives.

Response: EPA recognizes that transitioning to new foam blowing agents is likely to require capital costs and investments in research, updated equipment, and related financial impacts. However, as explained in more detail in another response to comment, under the SNAP criteria for review in 40 CFR 82.180(a)(7), the only cost information that EPA considers as part of its SNAP review is the cost of the substitute under review (and not the cost of transition when a substitute is found unacceptable).

Although cost is not a consideration in our decision to change the status of certain substitutes, we note that based on technical concerns, the final rule establishes a later change of status date in a number of end-uses, which will allow manufacturers to spread costs over time. Regarding whether there will

be a sufficient supply of alternatives, we considered this issue in establishing the change of status dates and believe that there will be more than adequate supplies of alternatives. This will also contribute to lower costs. We have addressed elsewhere why it is necessary to change the status of substitutes for the various end-uses based on whether alternatives that pose lower risk are available. Where we concluded that safer alternatives were available, we determined it was necessary to change the status. Thus, we disagree with the commenters who suggest that it is not necessary to change the status of various HFC foam blowing agents.

## VI. What is EPA finalizing for the HCFCs addressed in this rule?

A. What did EPA propose for HCFCs and what is being finalized in this rule?

In the August 6, 2014 NPRM, EPA proposed to change the listings from acceptable to unacceptable for three HCFCs: HCFC-141b, HCFC-142b, and HCFC-22 (79 FR 46155). As discussed in the proposed rule, EPA proposed to modify the listings for these three HCFCs and blends containing these HCFCs to align the SNAP listings with other parts of the stratospheric protection program, specifically section 605 and its implementing regulations at 40 CFR part 82 subpart A and section 610 and its implementing regulations at 40 CFR part 82 subpart C. HCFCs are subject to the use restrictions in CAA section 605(a) and these specific HCFCs have been restricted under EPA's implementing regulations at 40 CFR part 82 subpart A since January 1, 2010. Additionally, the nonessential products ban under CAA section 610 restricts sale and distribution of certain products containing or manufactured with these three HCFCs. We believe it is important that the SNAP listings not indicate that these HCFCs may be used when another program under title VI of the CAA would prevent such use. Thus, we are aligning the requirements. The HCFCs addressed in this rule were previously listed as acceptable or acceptable subject to use conditions in the aerosols, foam blowing, fire suppression and explosion protection, sterilants, and adhesives, coatings and inks sectors. For more information, please refer to the relevant section of the proposed rule as noted above. The change of status determinations for the HCFCs addressed in this rule are summarized in the following table:

Sector and end-use	Substitutes	Decision
Aerosols—Propellants	HCFC-22 and HCFC-142b	Unacceptable effective [DATE 60
	11050 444 111 1 11 1	DAYS AFTER PUBLICATION OF FINAL RULE]
Aerosols—Solvents	HCFC-141b and blends thereof	Unacceptable effective [DATE 60 DAYS AFTER PUBLICATION OF
Foams—All end-uses	HCFC-141b, HCFC-142b, HCFC-22, and blends	FINAL RULE] Unacceptable effective [DATE 60
Fig. 100 and 100 Table flooring	thereof	DAYS AFTER PUBLICATION OF FINAL RULE]
Fire suppression—Total flooding	HCFC-22	Unacceptable effective [DATE 60 DAYS AFTER PUBLICATION OF
Sterilants	Blends containing HCFC-22	FINAL RULE] Unacceptable effective [DATE 60
Adharing a saling a sadial a All and a sa	UOFO 44th and blands thereof	DAYS AFTER PUBLICATION OF FINAL RULE]
Adhesives, coatings, and inks—All end-uses	HCFC-141b and blends thereof	Unacceptable effective [DATE 60 DAYS AFTER PUBLICATION OF

TABLE 9—CHANGE OF STATUS DECISIONS FOR HCFCS ADDRESSED IN THIS RULE

Consistent with the proposal, in today's final rule, EPA is modifying the listings for HCFC–141b, HCFC–142b, and HCFC–22, as well as blends that contain these substances, from acceptable to unacceptable <sup>90</sup> in non-refrigerant sectors—specifically, aerosols, foam blowing agents, fire suppressants, cleaning solvents, sterilants, and adhesives, coatings and inks.

As provided in the proposal, EPA is not addressing HCFC use for refrigeration and air conditioning in this rulemaking because CAA section 605(a) and our implementing regulations allow for continuing use of HCFCs to service equipment. Recognizing that other HCFCs became subject to the use and interstate commerce prohibitions in 40 CFR 82.15(g) after issuance of the proposed rule, and that limited exemptions are available in section 82.15(g) for certain of those HCFCs, EPA is not modifying the SNAP listings for HCFCs other than HCFC-141b, -142b, and -22 and blends containing those substances at this time. EPA may revisit the acceptability of other HCFCs in a later rulemaking as appropriate. We are finalizing the proposal that the listings be modified 60 days following issuance of a final rule.

B. How is EPA responding to public comments concerning HCFCs?

Comment: EPA received a few comments on the proposed modifications affecting HCFCs, primarily on whether the unacceptability determination should apply to imported products containing closed cell foam that contain any of the blowing agents listed as unacceptable, as well as applying to the blowing agent itself.

Response: As explained in section V.D.2.c, above, EPA is not finalizing the proposed change to the import of closed cell foam products blown with an agent listed as unacceptable. We also explained that we plan to continue assessing the merits of this change and may provide further explanation and opportunity for comment in a subsequent rulemaking. Thus, as of the time of the status change, foam blowing agents containing HCFC-141b, -142b, and -22 and blends are prohibited from being used or imported into the United States, but foam products or products containing foam made with these agents, such as appliances or furniture, may still be imported.

Comment: Hussmann Corporation asked for four years from the issuance of the final rule to make any changes to the acceptability of HCFC–141b in foam blowing applications, stating that considerable time is needed to review what impact new foam has to structural integrity and product efficiency. The commenter stated that this timing would would allow manufacturers to make a transition to new products while remaining within the EPA's new HCFC allocation rule (which will completely phase out HCFC refrigerants in five years).

Response: EPA would like to clarify that anyone still using HCFC-141b to blow foam in the United States is likely out of compliance with longstanding regulations promulgated under the SNAP program (CAA section 612), as well as the HCFC phaseout (CAA section 605). Under SNAP, HCFC-141b was listed as unacceptable effective on November 29, 2004, for all foam uses,

with a limited exemption for use in space vehicle, nuclear, and defense applications, as well as for research and development for foreign customers (see 69 FR 58269). Under the HCFC phaseout program, EPA stopped the production and import of HCFC-141b for use in foams in 2003 (40 CFR 82.16(b)) and prohibited its use as of January 1, 2010, with limited exceptions (40 CFR 82.15(g)). All remaining exemptions for the use of HCFC-141b ended on January 1, 2015. Therefore, this current rule does not affect the use of HCFC-141b to blow foam in the United States; it only ensures the SNAP list is aligned with other existing regulations under Title VI of the CAA.

FINAL RULE]

If the commenter is referring to applying the unacceptability determination for HCFC–141b to products containing HCFC–141b, as discussed above in this section, EPA is not finalizing the proposed change to the import of closed cell foam products blown with an agent listed as unacceptable.

# VII. How is EPA responding to other public comments?

## A. Authority

### 1. General Authority

Comment: The Agency received several comments, including those from Solvay, Arkema, AHAM, BASF, Mexichem, NRDC and IGSD, Whirlpool, and Bally Refrigerated Boxes on its authority to change the status of HFC–134a and other substitutes that were addressed in the proposed rule. NRDC and IGSD asserted that under section 612 of the CAA ((42 U.S.C. 7671k), EPA has the authority—if not the affirmative mandate—to remove the proposed substances from the SNAP list of

 $<sup>^{90}\,\</sup>mathrm{These}$  three HCFCs have previously been listed as unacceptable in several, but not all, SNAP sectors.

acceptable substitutes. They quoted from section 612(a), emphasizing that replacement of ODS with substitutes that reduce overall risk is to occur "to the maximum extent practicable" (42 U.S.C. 7671k(a)). They stated that under section 612(c)(2), EPA has authority to decide which substances may and may not be used in the SNAP sectors. Finally, they asserted that in speaking of both alternatives "currently" available, and those that are "potentially" available, Congress recognized that the universe of alternatives will evolve over time, so that as additional alternatives become available, EPA has an obligation to revise the SNAP list to ensure that the substances included will minimize "overall risks to human health and the environment" (42 U.S.C. 7671k(c)).

In contrast, Mexichem, Solvay, AHAM/Electrolux and Arkema asserted that the proposed actions were outside the scope of Title VI, section 612 of the CAA, and EPA's SNAP regulations. Specifically, these commenters asserted that Congress and EPA designed the SNAP program to safeguard stratospheric ozone, and not to address climate change and greenhouse gases. AHAM stated that Title VI of the CAA does not provide EPA broad authority to regulate refrigerants, foams and chemicals in circumstances unrelated to ozone depletion. Mexichem stated that the repeated references in section 612 to class I and class II substances demonstrate that Congress was concerned with ODS.

Several commenters emphasized evaluation of a substitute in relation to ODS. Mexichem asserted that EPA recognized "the limited nature of the statute" in 1994 when it promulgated the statement of purpose and scope for the SNAP program (59 FR 13044, Mar. 18, 1994; 40 CFR 82.170). In its comment, Mexichem provided a quotation from the statement of purpose and scope, suggesting that substitutes are to be compared only to ODS. Arkema quoted an EPA "Guide to Completing a Risk Screen" 91 for the fire suppression sector as explaining that environmental effects would be evaluated by comparing the substitute's GWP to the GWP of the ODS it replaces. Solvay contended that changing the listing status of a previously approved substitute would eliminate the user's ability to use a substance that met the statutory objective of providing better overall health and safety in comparison to the use of an ODS in a specific endSeveral commenters also asserted that nothing has happened with respect to any attribute or impact of the HFCs addressed in this rulemaking that would warrant a change in the initial decisions to list HFCs as acceptable.

Response: EPA agrees with NRDC and IGSD's conclusion that the Agency has authority to take the change of status actions included in the proposed rulemaking and disagrees with comments suggesting that the sole purpose of section 612 and the SNAP program is to safeguard the ozone layer. Section 612(c) requires EPA to take action when the Agency (1) determines that a substitute may present adverse effects to human health and the environment, and (2) identifies an alternative that reduces overall risk to human health and the environment and is currently or potentially available. That provision makes clear that the mandate of section 612 is to reduce overall risk; it does not limit the risks of concern to those associated with ozone depletion. In addition, while section 612 refers repeatedly to class I and class II substances, it also refers repeatedly to substitutes or alternatives, requiring specific actions with regard to such substances.

EPA cannot fulfill its section 612(c) mandate to compare alternatives with a view to reducing overall risk without considering impacts related to issues other than ozone depletion. Toward that end, the SNAP regulations require submitters to include information on a wide range of factors in addition to ODP, including GWP, toxicity flammability, and the potential for human exposure (59 FR 13044, Mar. 18, 1994 and codified at 40 CFR 82.178). Further, the SNAP regulations state that EPA will consider atmospheric effects (including GWP), exposure assessments, toxicity data, flammability, and other environmental impacts such as ecotoxicity and local air quality impacts (59 FR 13044, Mar. 18, 1994; 40 CFR

In addition, while section 612(a) states the Congressional policy of reducing overall risk in broad terms. section 612(c) specifically requires EPA to compare the risk of the substitute under review to other substitutes or alternatives. In that regard, Mexichem's comment omits a crucial phrase in the statement of "purpose and scope" in the SNAP regulations. The complete statement reads: "The objectives of this program are . . . to promote the use of those substitutes believed to present lower overall risks to human health and the environment, relative to the class I and class II compounds being replaced, as well as to other substitutes for the

same end-use, and to prohibit the use of those substitutes found, based on the same comparisons, to increase overall risks [emphasis added]" (59 FR 13044, Mar. 18, 1994; 40 CFR 82.170). In addition, Arkema's reference to a single document containing language mentioning a substitute-to-ODS comparison ignores the large number of risk screens that EPA has prepared over the years that compare the ODP and GWP, and other environmental and health attributes, of substitutes to those of other substitutes, as well to those of ODS (e.g., risk screens in the following dockets: EPA-HQ-OAR-2013-0798 and EPA-HQ-OAR-2003-0118.) Further, EPA's listings over the years have included comparisons of substitutes to other available alternatives in the same end-uses (e.g., 67 FR 13272, 67 FR 77927, 68 FR 50533, 69 FR 58903, 71 FR 15589, 71 FR 55140, 71 FR 56359, 74 FR 21, 74 FR 50129, 75 FR 34017, 76 FR 17488, 76 FR 61269, 76 FR 78832, 77 FR 47768, 77 FR 58035, 78 FR 29034, 79 FR 62863). The substitute-to-substitute comparison is essential to fulfilling EPA's obligation under section 612(c) to determine whether there are alternatives that reduce overall risk as compared with the substitute under review.

To the extent possible, the Agency has always sought to ensure that our SNAP decisions are informed by the most current overall understanding of environmental and human health impacts associated with available and potentially available alternatives. In that regard, the Agency has, since the inception of the SNAP program, asserted its authority, consistent with the language of section 612(c) and the section's statement of congressional policy, to review substitutes listed as acceptable and to take action with respect to those substitutes on the basis either of new information generally, including that related to overall risk, or of the availability of new alternatives that pose less overall risk. Specifically, in the preamble to the initial SNAP rule, EPA made clear that "the Agency may revise these [listing] decisions in the future as it reviews additional substitutes and receives more data on substitutes already covered by the program" (59 FR 13044, 13047). We interpret section 612 as allowing both addition of new, safer alternatives to the listings and removal from the listings of substitutes found to pose more risk overall than other available alternatives.

With regard to additional data on substitutes already covered by the program, the Agency has previously responded to the evolution of scientific and technical information by revisiting the listing status of a substitute. For

<sup>91</sup> http://www.epa.gov/ozone/snap/fire/ riskscreenfire.pdf

example, on the basis of new information on toxicity, EPA took action in January of 2002 to change the listing for HBFC-22B1 from acceptable, subject to use conditions to unacceptable (67 FR 4185, January 29, 2002; 40 CFR 82 subpart G, appendix J).

With regard to additional alternatives, the suite of available or potentially available alternatives changes over time. For example, over the past several years, and as standards and familiarity with the safe use of various alternatives has developed, EPA has listed several specific flammable refrigerants as acceptable for some end-uses subject to use conditions (e.g., 76 FR 78832, December 20, 2011; 40 CFR 82 subpart G appendix R; 80 FR 19453, April 10, 2015). Most of these refrigerants (e.g., ethane, propane, isobutane, HFC-32) are not new molecules; rather, their recent listing as acceptable subject to use conditions is based on an increased understanding of their ability to be used in a manner that would reduce overall risk. The availability of those alternatives enables a broader review of comparative risk under section 612(c).

Further, we disagree with the notion that our understanding of the impact of HFCs has remained static. Our understanding of the impact that HFCs have on climate has evolved and become much deeper over the years. As mentioned elsewhere in this rulemaking, a significant indication of that change can be seen in EPA's December 7, 2009, Endangerment Finding (74 FR 66496, 66517, 66539) which makes clear that like the ODS they replace, HFCs are potent GHGs. In addition, HFCs are now in widespread usage. The most commonly used HFC is HFC-134a. HFC-134a is 1,430 times more damaging to the climate system than carbon dioxide (see Table A-1 to subpart A of 40 CFR part 98). Further, HFC emissions are projected to accelerate over the next several decades; if left unregulated, emissions are projected to double by 2020 and triple by 2030.92 Additional information concerning the peer-reviewed scientific literature and emission scenarios related to HFCs is available in the docket for this rulemaking (e.g., Akerman, 2013; EPA, 2013b and 2014; IPCC, 2007 and 2013: IPCC/TEAP 2005: Montzka, 2012: Velders et al., 2009). This information was taken into account in this rulemaking.

#### 2. Second Generation Substitutes

Comment: Several comments focused on the term "replace" in section 612(c), suggesting that once a company has switched to a non-ODS alternative, it is no longer "replacing" a Class I or Class II ODS in its products, and that it is unsupportable to read "replacement" as a continuous process rather than as a single event. Solvay stated that the proposed rule would require users that have already "replaced" ODS with non-ODS to make a second replacement, and that EPA lacks authority to require this second replacement. Arkema stated that the statutory terms "replace" and "replacement" must be given their ordinary meanings, and that to replace an ODS means to take the place of an ODS. Arkema further noted that EPA defines a "substitute or alternative" in its SNAP regulations as something "intended for use as a replacement for" an ODS (59 FR 13044, Mar. 18, 1994 and 40 CFR 82.172). Arkema concluded that Congress and EPA designed the SNAP program to regulate things taking the place of ODS, not to replace substances with no ozone depletion potential. Arkema contended that EPA has interpreted the statute and regulations as excluding non-ODS. In support of this argument, Arkema quoted the preamble to the initial SNAP rule as saving that "a key issue" was "whether there exists a point at which an alternative should no longer be considered a class I or class II substitute as defined by 612" (59 FR 13044, 13052). The commenter further quoted the preamble to that rule as saying that "if a hydrofluorocarbon (HFC) is introduced as a first-generation refrigerant substitute for [an ODS], it is subject to review and listing under section 612. Future substitutions to replace the HFC would then be exempt from reporting under section 612 . . . . " ( $\mathit{id}$ .). In addition, Arkema quoted a 1996 petition response 93 as stating that EPA does not review substitutes for non-ozonedepleting substances such as HFC-134a. Arkema also quoted the SNAP Instruction Manual 94 as instructing applicants to specify the ODS being

replaced.
AHAM commented that the appliance industry no longer intends HFCs as a substitute or replacement for ODS. The commenter stated that there are very few remaining models that ever used ODS, and that the substances used in today's models are not substitutes or

replacements in the common-sense meaning of those words.

Arkema further stated that EPA should be precluded from comparing non-ODS first-generation alternatives (such as HFC–134a) to second-generation non-ODS alternatives (such as HFO–1234yf, HFC–152a, and R–744). Arkema contended that none of these second-generation compounds is a "substitute" for SNAP purposes.

Response: In this rulemaking, the Agency is revising the listing status of substitutes that are direct replacements for ODS. Arkema admits as much on p. 8 of their comment letter, where they describe HFC-134a as a "first generation refrigerant substitute." While we are not exploring the full scope of the "first generation" concept in this action, there is no question that HFC–134a directly replaced ODS in the relevant sectors. For example, with respect to foam blowing, when HFC-134a was listed as acceptable in foam blowing applications, foam was still being blown with HCFCs (59 FR 13044, March 18, 1994; 64 FR 30410, June 8, 1999). In this action, we are not addressing the extent of EPA's authority to revise the listings of alternatives that are arguably indirect replacements for ODS, sometimes termed "second-generation alternatives."

EPA does not agree with the commenters who suggest that while HFC-134a may have replaced ODS at one point in time, it no longer does so. The term "replace" is not defined in section 612, EPA therefore interprets this term as it is commonly used. Dictionary definitions can provide insight into how a reasonable or ordinary person would interpret the term. Dictionary definitions of "replace" include the following: "to be used instead of" 95 "to take the place of," 96 and "to provide a substitute or equivalent for." 97 None of these definitions suggests that something used "instead of" or "to take the place" of something else ceases to "replace" it simply due to the passage of time. Nor does the Agency view the replacement of a ODS with a substitute (e.g., HFC-134a) as limited to the first time a product manufacturer uses the substitute. Indeed, in the preamble to the initial SNAP rule, we interpreted the term "replace" to apply "each time a substitute is used." (59 FR 13044, 13047). We noted that "[u]nder any other interpretation, EPA could never

<sup>&</sup>lt;sup>92</sup> Climate Change and President Obama's Action Plan. June, 2013. Available in the docket and online at www.whitehouse.gov/share/climate-action-plan.

<sup>&</sup>lt;sup>93</sup> Response to Oz Technology's Petition (Aug 30, 1996).

<sup>&</sup>lt;sup>94</sup> www.epa.gov/ozone/snap/submit/ appguide.pdf.

<sup>&</sup>lt;sup>95</sup> Merriam-Webster, http://www.merriam-webster.com/dictionary/replace.

 $<sup>^{96}</sup>$  Collins, www.collins dictionary.com/dictionary/american/replace.

<sup>97</sup> Id.

effectively prohibit the use of any substitute, as some user could always start to use it prior to EPA's completion of the rulemaking required to list it as unacceptable" ( $\widecheck{Id}$ .). Thus, the fact that HFC-134a is already in use as a replacement for ODS does not mean that its future use is any less of a replacement. In context, the language that Arkema quotes ("whether there exists a point at which an alternative should no longer be considered a class I or II substitute") does not suggest that a substance that directly replaces the ODS might somehow cease to qualify as an ODS substitute. Rather, it raises the question of whether a substance that indirectly replaces the ODS might fail to qualify. That question is not addressed in this rulemaking because this rulemaking addresses only substances that are direct replacements for ODS in the relevant sectors.

Similarly, the mere passage of time does not mean that the substances addressed in this rulemaking have somehow ceased to be "substitutes or alternatives" under the regulatory definition at 40 CFR 82.172. No commenter suggests that at the time of their initial SNAP listing these substances were anything other than "chemicals . . . intended for use as a replacement for a class I or II compound." Rather, commenters assert that these substances are no longer intended for use as an ODS replacement. However, introducing a temporal aspect into this definition would mean that a product manufacturer could make an initial substitution for a class I or II substance 90 days after providing the required notification to EPA and thereafter continue to use the substitute while disclaiming any intent to replace the ODS. This is not a supportable interpretation because it would allow the manufacturer to circumvent SNAP requirements simply by beginning to use a substitute prior to its SNAP listing.

In addition, EPA implements the section 612(c) mandate to list substances as acceptable or unacceptable "for specific uses" by listing substitutes on an end-use or sector basis. 98 Similarly, the Agency views transition as occurring on an end-use by end-use or sector-by-sector basis, not—as one commenter suggests—on a model-by-model basis. Thus, the act of "replacing" is not limited to the redesign of a particular model, or the introduction of a new model, but

instead occurs repeatedly within a given end-use or sector.

Contrary to Solvay's comment, EPA has authority to regulate the continuing replacement of ODS with HFC-134a and the other substitutes whose listing status is addressed in this action. In this rulemaking, EPA considered whether such replacement should continue to occur given the expanded suite of other alternatives to ODS in the relevant enduses and our evolving understanding of risks to the environment and public health. The commenter's line of reasoning would undermine EPA's ability to comply with the statutory scheme reflected in section 612(c), under which EPA's authority to prohibit use of a substitute is tied to information on overall risk and the availability of

Regarding Arkema's suggestion that HFO-1234yf, HFC-152a, and R-744 are not "substitutes" for SNAP purposes and thus they cannot be used as part of a review of whether EPA should change the status of HFC-134a, we disagree. HFO-1234yf, HFC-152a and R-744 (as well as the other substances we used for comparison purposes in this rulemaking) 99 are currently listed as acceptable or acceptable, subject to use conditions under SNAP. Thus, we have separately taken action to treat these substances as substitutes for the purposes of section 612(c) and the corresponding regulatory provisions. We are not re-examining in this rulemaking whether the substances used for comparison purposes in this action qualify as substitutes. Rather, in this rule, we are making listing determinations for substances that are direct substitutes for ODS based on their overall risk compared to these other alternatives.

## 3. GWP Considerations

Comment: The Agency received several comments relating to EPA's authority to consider GWP in its comparative risk evaluation, and to take action on the basis of GWP. Specifically, Solvay and Mexichem stated that while section 602 of the CAA requires EPA to publish the GWP of each listed class I and class II substance, the Agency's authority is limited by the language stating that it "shall not be construed to be the basis of any additional regulation under this chapter." Solvay stated that this language expresses Congress's intent that no provision of Title VIincluding, but not limited to, § 602, § 608, § 612, and § 615—provides statutory authority for the Agency to implement an overarching program under which it can force users to cease using substances with global warming, but not ozone-depleting, potentials. Mexichem commented that if GWPs of listed compounds cannot be the basis of further regulation under Title VI, it follows that regulation based on comparisons of GWPs of both listed substances and unlisted alternatives was intended by Congress equally to be foreclosed. Commenters asserted that EPA inappropriately used the physical characteristic of GWP as a surrogate for risk; failed to assess the significance to climate change of the emissions reductions estimated to be brought about by the action as they relate to risk for each substance in each sector covered; failed to assess and account for indirect climate impacts; and failed to apply its customary tests for consideration of atmospheric effects.

BASF commented that EPA proposed to find HFCs unacceptable because they have "high GWPs as compared with other available or potentially available substitutes in those end-uses and pose significantly greater overall risk to human health and the environment." BASF noted that while CAA section 612 does require an assessment of risk, it does not explain how that assessment should be done. BASF added that whatever that assessment should involve, it is possible that Congress did not intend GWP to be part of that assessment.

Response: As noted by some commenters, section 602 of the CAA calls on EPA to publish the GWP for each class I or class II substance, but goes on to say that this mandate "shall not be construed to be the basis of any additional regulation under this chapter." Consistent with this provision, we are not relying on section 602 as authority for the action being taken in this rulemaking. Rather, we are relying on section 612, which specifically provides that EPA is required to list a substance as unacceptable if it "may present adverse effects to human health or the environment" where EPA has identified

 $<sup>^{\</sup>rm 98}\,\rm This$  is reflected in the appendices to 40 CFR part 82, subpart G.

 $<sup>^{99}</sup>$  We note that the requirement under section 612 does not limit our analysis of whether there are "safer" alternatives only to "substitutes" listed under the SNAP program. Rather section 612(c) refers to "alternatives" that are currently or potentially available. Thus, in instances where we are aware of other alternatives that may not have completed SNAP review and we have sufficient information for those alternatives relative to the SNAP review criteria, we may include those alternatives in our comparative analysis. In this action, for purposes of the refrigeration end-uses, we included in our comparative analysis several substances we were concurrently reviewing under SNAP and which we have taken action to list as acceptable, subject to use conditions (April 10, 2015, 80 FR 19453) and for which we are taking action concurrently with this rule to list as acceptable.

alternatives that are currently or potentially available and that "reduce the overall risk to human health and the environment."

Considerations of atmospheric effects and related health and environmental impacts have always been a part of SNAP's comparative review process, and the provision of GWP-related information is required by the SNAP regulations (see 40 CFR 82.178 and 82.180). The issue of EPA's authority to consider GWP in its SNAP listing decisions was raised in the initial rule establishing the SNAP program. In the preamble to the final 1994 SNAP rule, EPA stated: "The Agency believes that the Congressional mandate to evaluate substitutes based on reducing overall risk to human health and the environment authorizes use of global warming as one of the SNAP evaluation criteria. Public comment failed to identify any definition of overall risk that warranted excluding global warming" (59 FR 13044, March 18, 1994).

Consistent with that understanding, the 1994 SNAP rule specifically included "atmospheric effects and related health and environmental impacts" as evaluation criteria the Agency uses in undertaking comparative risk assessments (59 FR 13044, March 18, 1994; 40 CFR 82.180(a)(7)(i)). That rule also established the requirement that anyone submitting a notice of intent to introduce a substitute into interstate commerce provide the substitute's GWP (see 40 CFR 82.178(a)(6)). Accordingly, we have considered the relative GWP of alternatives in many SNAP listing decisions. For example, in the decision to list C7-Fluoroketone as acceptable we noted that "C7 Fluoroketone's GWP of about 1 is lower than or comparable to that of other non-ozone-depleting substitutes in heat transfer uses, such as HFE-7100 with GWP of 297, HFC-245fa with a GWP of 1030, and CO<sub>2</sub> with a GWP of 1" (77 FR 47768, August 10, 2012). In that same action, EPA also considered ODP, VOC status, flammability, toxicity and exposure, concluding that "EPA finds C7 Fluoroketone acceptable in the end-use listed above because the overall environmental and human health risk posed by C7 Fluoroketone is lower than or comparable to the risks posed by other substitutes found acceptable in the same end-use" (id). Similarly, in finding the use of isobutane and R-441 acceptable subject to use conditions in household refrigeration, we included an-in depth discussion of the relative GWP of these and other alternatives

listed for household refrigeration (76 FR 78832, December 20, 2011).

In response to comments that EPA inappropriately used the physical characteristic of GWP as a surrogate for risk and that EPA failed to assess the significance to climate change of the emissions reductions estimated to be brought about by the action, as they relate to risk for each substance in each sector covered, we note that GWP is a relative measure and that if comparable amounts of two substitutes are used, then the relative climate effects of resultant emissions will be higher for the substitute with higher GWP. EPA considers factors such as charge size of refrigeration equipment and total estimates of production in its assessment of environmental and health risks of new alternatives, so we can consider if there would be substantial differences that might affect total atmospheric emissions. We believe that we have appropriately considered GWP as a metric for comparing climate effects of substitutes.

In response to comments that EPA failed to assess and account for indirect climate impacts, we note that we do not have a practice in the SNAP program of including indirect climate impacts in the overall risk analysis. We do consider issues such as technical needs for energy efficiency (e.g., to meet DOE standards) in determining whether alternatives are "available," and have followed that practice in this rulemaking. We believe that there is a sufficient range of acceptable alternatives that end users will be able to maintain energy efficiency levels We also note that federal energy conservation standards will continue to ensure that equipment regulated by this rule will not increase its indirect climate impacts. See in particular section V.C.7 for a discussion on energy efficiency for commercial refrigeration products and section V.D.3.c for a response to comments on energy efficiency of foams.

In this action, EPA used the same comparative risk approach it has used in the past, including the consideration of GWP.

### 4. Takings

Comment: Solvay asserted that the delisting of already approved alternatives constitutes a taking in violation of the Fifth Amendment to the U.S. Constitution. Solvay commented that the delisting would effectuate a regulatory taking for which the United States would owe "just compensation" to regulated parties, including Solvay, that have made significant investments in furtherance of U.S. policies under the

CAA and the Montreal Protocol. Solvay quoted the Supreme Court case *Lucas* v. *South Carolina Coastal Council* as saying that "any limitation [that prohibits all economically beneficial uses of real property] . . . cannot be newly legislated or decreed (without compensation), but must inhere in the title itself, in the restriction that background principles of the State's law of property and nuisance already place upon land ownership" (505 U.S. 1003, 1029 (1992)).

Response: The first question in a takings analysis is whether there is a property interest protected by the Fifth Amendment. The commenter does not identify the property interest that is the subject of the alleged "taking." While the commenter cites a case involving real property, no real property is at stake here. To the extent the commenter has a property interest in the HFCs it imports or produces, such interest would be limited to quantities already in existence, and not those that might be produced or imported in the future. In any event, EPA's change in the listing status of HFCs does not effectuate a taking. First, EPA's action does not "completely deprive" the commenter of "all economically beneficial us[e]" of the HFCs it produces or imports. See Lingle v. Chevron, 544 U.S. 528, 538 (2005), quoting Lucas v. South Carolina Coastal Council, 505 U.S. 1003, 1019 (1992). EPA is not listing all HFCs as unacceptable in all end-uses; rather, EPA is listing certain HFCs as unacceptable in specified end-uses. In addition, EPA is adopting change of status dates that provide ample time for HFCs already in existence to be sold. Thus, some "economically beneficial use" of the HFCs remains. In such situations, courts typically consider several factors in determining whether a regulatory taking has occurred. Those factors include "the character of the governmental action, its economic impact, and its interference with reasonable investment-backed expectations." PruneYard Shopping Center v. Robbins, 447 U.S. 74, 83 (1980).

Here, the change in the listing status of certain HFCs for specified end-uses is designed to "promote the common good" (see Penn Central Transportation Co. v. New York City, 438 U.S. 104, 124 (1978)). The alternatives to which EPA compared these HFCs in this action were found to pose less overall risk to human health and the environment in the specified end-uses. Thus, removing these HFCs from the list of acceptable substitutes for these end-uses provides a public benefit. Regarding the economic impact of this action, EPA recognizes

that the impact will vary for the different end-uses. For example, for some foam blowing agent end-uses, transitioning to other alternatives is likely to require capital costs and investments in research, updated equipment, and their related financial impacts. In comparison, for some aerosol propellant uses and some refrigeration end-uses, depending on the alternative selected, there may be little or no need for capital costs or research. However, EPA notes that chemical producers have been investing in low-GWP alternatives for years, and many have either submitted SNAP notifications or expressed interest in submitting SNAP notifications concerning new molecules and blends of existing molecules.

The commenter could not have had a reasonable investment-backed expectation that these HFCs would continue to be listed as acceptable indefinitely in all end-uses, or in any specific end-use, because EPA expressly stated in the preamble to the initial SNAP rule that "the Agency may revise these [listing] decisions in the future as it reviews additional substitutes and receives more data on substitutes already covered by the program" (59 FR 13044, 13047). In addition, EPA also noted the "significant global warming potentials" of some HFCs and stated "EPA is concerned that rapid expansion of the use of some HFCs could contribute to global warming" (id. at 13,071). EPA characterized HFCs as a "near-term option for moving away from CFCs," not as a long-term solution.

### 5. Montreal Protocol/International

Comment: Solvay comments that HFCs are not regulated under the Montreal Protocol and are not Class I or Class II substances under Title VI. Mexichem states that the United States, Canada, and Mexico have proposed to amend the Montreal Protocol to provide an across-the-board phase down of HFCs, but until then, EPA's regulatory authority under Title VI is limited to ODS. AHAM adds that if at some point EPA is authorized to phase out HFCs consistent with future international obligations that may constitute a more appropriate avenue for phase-down measures. AHAM believes there is minimal purpose in promoting an international regulatory regime if EPA is going to apply what it considers to be a "blunt and inappropriate" regulatory instrument domestically, regardless of the shape of a future international scheme. AHAM comments that the appliance industry's transition from HFCs is well underway, and EPA's proposal should reflect and support this

progress, rather than impede it. Five commenters commented on the perceived inconsistency of the proposed timeline and the proposed amendments to the Montreal Protocol to adopt a gradual phase down of HFCs.

Response: EPA agrees that the Montreal Protocol does not currently regulate HFCs. Nevertheless, several sections of Title VI call on EPA to take measures that are not required by the Montreal Protocol but are complementary to the ODS phaseout. These sections include, in addition to section 612, sections 608 (national emissions reduction program), 610 (nonessential products), and 611 (labeling). In addition, while HFCs are not a Class I or Class II substance under the Clean Air Act. HFCs are substitutes for Class I and Class II ODS, and section 612 and its implementing regulations specifically call on the agency to restrict substitutes for ODS where the Agency has identified other available or potentially available alternatives that reduce overall risk to human health and the environment.

The CAP considers both domestic and multilateral action to address HFCs. The United States co-proposed and is strongly advocating for an amendment to the Montreal Protocol to phase down production and consumption of HFCs. EPA sees no conflict between the United States' strong support for a global phasedown and this domestic action. The amendment proposal calls for a phasedown of production and consumption of a group of HFCs, including HFC–134a as well as HFC-125 and HFC-143a (components of R-404A, R-507A and other blends), on a total CO<sub>2</sub>-equivalent basis. It applies phase-down steps to this group of HFCs as a basket and does not assign individual deadlines to specific HFCs or address specific uses.

#### 6. Absence of Petitions

Comment: Solvay questioned whether the Agency has the authority to issue this proposed rule in the absence of one or more petitions that fully satisfy the requirements of § 612(d). Solvay commented that while Congress granted EPA the authority to create an initial list of approved substitutes for ODS under § 612(c), § 612(d) specifies that additions or deletions to the SNAP list must be proposed via petition, and that petitions "shall include a showing by the petitioner that there are data on the substance adequate to support the petition." Solvay stated that the CAA puts the burden on a petitioner to demonstrate that the substance it proposes to list satisfies all of the SNAP criteria. Solvay contended that EPA should not attempt to delist any

substances on its own initiative. Solvay commented that to the extent it does, EPA has the burden, standing in the shoes of a petitioner, to demonstrate that it has data adequate to support the petition.

Response: The Agency disagrees with the commenter regarding EPA's authority to independently review and, where appropriate, change the status of substitutes under the SNAP program. In the preamble to the initial SNAP rule, the Agency stated that "section 612 authorizes it to initiate changes to the SNAP determinations independent of any petitions or notifications received. These amendments can be based on new data on either additional substitutes or on characteristics of substitutes previously reviewed" (59 FR 13044, 13047). Nothing in section 612(c) contravenes this interpretation. The existence of section 612(d), which provides a right for persons to petition the Agency to revise a listing, does not address in any manner whether EPA has authority to change a listing on its own. Furthermore, section 612(c) requires EPA to take action when the Agency (1) determines that a substitute may present adverse effects to human health and the environment, and (2) identifies an alternative that reduces overall risk to human health and the environment and is currently or potentially available. Section 612(c) does not limit such EPA determinations to initial review of substitutes.

For petitions under section 612(d), the petition must "include a showing . . . that there are data on the substance adequate to support the petition." The Agency disagrees that EPA stands in the shoes of a petitioner under 612(d) when it proposes to change the listing status of an alternative. Rather, EPA's action is governed by section 612(c), and EPA considers the criteria used in reviewing substitutes as provided in 40 CFR 82.180(a)(7). Regardless, we note that we also review section 612(d) petitions based on the same SNAP criteria and thus the "data on the substance adequate to support the petition" necessarily are the data required for review under 40 CFR 82.180(a)(7).

EPA has changed the listing status of substitutes in the past without having received a petition under section 612(d), as, for example, when we changed the listing status of MT–31 (64 FR 3861, Jan. 26, 1999; 40 CFR part 82 subpart G appendix E) and HBFC–22B1 (67 FR 4185, Jan. 29, 2002; 40 CFR part 82 subpart G appendix J).

While EPA has the right to act in the absence of a petition, as described above, EPA did receive three petitions filed under section 612(d) that are

relevant to this rulemaking. Specifically, NRDC filed a petition on May 7, 2010. On February 14, 2011, EPA found that petition complete for MVAC in new passenger cars and light-duty vehicles and determined it was incomplete for other uses of HFC-134a. This rule responds to the aspect of that petition that we found complete. In addition, EIA filed a petition on April 26, 2012, and NRDC, EIA, and IGSD filed a petition on April 27, 2012. Although EPA found both of these petitions incomplete, our action in this final rule may be considered responsive to certain aspects of the petitions, given that we are changing the listing of certain HFCs used in sectors noted in those petitions from acceptable to unacceptable for most uses, and placing use conditions or narrowed use limits on some of the remaining uses. A more detailed discussion of the petitions can be found in section IV of this rule.

## 7. Application of Criteria for Review of Alternatives

Comment: Solvay commented that EPA has failed to properly apply the SNAP factors to a delisting situation, has given undue weight to GWP in its analysis, and has based its decision on comparative GWPs of various non-ODS options to the exclusion of all other factors. Solvay commented that the proposal was deficient in that EPA failed to consider many relevant codes, standards and regulations, including parallel energy efficiency regulations issued by the DOE; building code standards; fire code requirements; and Coast Guard regulations. Solvay also stated that EPA should have considered technical concerns like solubility, compatibility, and shelf stability; equipment limits; supply chain considerations; and safety concerns that affect many end-use products.

Solvay further commented that in making a determination whether to list a substance as an approved substitute to replace an ODS, the Agency must conduct a comprehensive analysis of each alternative in each end-use, including considerations of the cost of the alternative, availability, and the overall practicability of effectuating a replacement. Solvay focused on the phrase "to the maximum extent practicable" in section 612(a) of the CAA, stating that Congress deliberately chose the term "practicable" to mandate an orderly transition from ODS. Solvay stated that the term "practicable" ordinarily includes consideration of cost and availability. Solvay further argued that EPA had acknowledged and agreed with this understanding of the term by including cost and availability in its list

of criteria. Solvay referred to dictum in *Honeywell* v. *EPA*, 374 F.3d 1363, 1373 (D.C. Cir. 2004) stating that "it is at least facially plausible to read the term 'available' in section 612(c) as permitting consideration of 'economic or practicality' concerns."

Mexichem commented that the text of the proposed rule and the underlying docket, including the SNAP program's comparative risk framework, are vague on how EPA reached the required section 612(c) conclusion that the alternatives reduce overall risks to human health and the environment, leaving the impression that it considered only GWP. Specifically, they state that out of the seven documents that may be relevant to the comparative risk framework analysis, only the "Climate Benefits of the SNAP Program Status Change Rule" report refers to human health and the environment, with a focus on climate benefits, but that the report itself is silent on estimated reduction of "overall risks to human health." Mexichem also noted that EPA promised to prepare a consolidated analysis document in the proposed rule, but no such document was available at the time the comments were drafted. Mexichem further stated that an assessment of HFC-134a and related alternatives is missing, and that such an assessment should have included several specific questions related to the following factors: Performance, availability, hazard, exposure, and cost of the alternatives. These questions include whether the other alternatives perform as well as HFC-134a in the specific end-use; whether the other alternatives will be available in the necessary quantities; whether the other alternatives present a better overall hazard profile; whether the other alternatives present a better overall exposure profile; whether use of the other alternatives involves an equivalent cost; and whether use of the other alternatives represents a costeffective mitigation of CO<sub>2</sub> emissions in each end-use.

Bally Refrigerated Boxes, Inc. questioned whether the CAA authorizes EPA to delist non-ODS solely on the basis of GWP. Arkema commented that EPA is focusing on the potential hazard of GWP alone and stated that EPA is not evaluating HFC-134a within a comparative risk framework. Arkema stated that if the CAA were to authorize the SNAP program to "delist" previously approved non-ozone depleting substances based on climate, then EPA would need to develop an objective measure for deciding which substitute poses a greater risk and communicate that standard to the

regulated community. Arkema claimed that any such measure would need to include methods for weighing different types of risks against one another (such as flammability versus climate) and for including mitigation, as the existing SNAP program, which did not originally provide for quantitative indexing of risks, does not convey sufficient information to the Agency or the regulated community regarding risk management decisions.

Response: EPA disagrees with the commenters' views regarding the Agency's consideration of overall risk. In this rule, we applied the same comparative risk framework that was established for the SNAP program in 1994 and that has been used successfully for over 20 years. When we issued the proposal, we did not re-open fundamental parts of the SNAP program, such as the factors we evaluate and the manner in which we weigh them. Under the SNAP regulations, proponents of a substitute are required to submit a wide array of information, including information on ODP, GWP, toxicity, environmental fate and transport, flammability, exposure data and the cost and availability of the substitute under review (see 40 CFR 82.178 for a full list of the information required with SNAP submissions). EPA reviews these data and applies the regulatory criteria adopted in 1994, which include, in addition to atmospheric effects, general population risks from ambient exposure to compounds with direct toxicity and to increased ground-level ozone, ecosystem risks, occupational risks, consumer risks, flammability, and cost and availability of the substitute under review (see 40 CFR 82.180(a)(7)). As regards specific quantification of reductions in overall risk to human health and the environment, in the 1994 rulemaking, we considered and rejected comments suggesting that we develop an index to rank all substitutes based on risk. In the preamble to the rule, we specifically noted that "a strict quantitative index would not allow for sufficient flexibility in making appropriate risk management decisions" (59 FR 13044, March 18, 1994). Our subsequent experience with the SNAP program has given us no reason to revisit this approach.

While EPA prepared a variety of documents in association with the proposed rule, the bulk of the comparison of human health and environmental impacts of alternatives appeared in the preamble to the NPRM.<sup>100</sup> For this final rule, we have added a technical support document to the docket which provides the **Federal Register** citations for information such as ODP, GWP, VOC status, flammability, and workplace exposure limits both for the substitutes remaining acceptable and for those with a changed status (EPA, 2015d). This information was discussed in the preambles to both the NRPM and the final rule and is provided in tabular format in the technical support document for easier comparison and consistency of presentation.

As stated in the NPRM, the documentation associated with the proposed rule includes "market characterizations, analyses of costs associated with sector transitions, estimated benefits associated with the transition to alternatives, and potential small business impacts" (79 FR 46126). These documents provide information to the public about estimated environmental benefits, the affected markets, and potential cost impacts, as well as provide EPA's screening analyses to determine whether this rule may have significant economic impacts or significant impacts on a substantial number of small businesses; they are not part of EPA's comparison of human health and environmental effects of alternatives.

Mexichem noted in its comments that EPA had included these documents in the docket for the proposed rule, but raised a concern about the availability of the consolidated analysis document anticipated in the NPRM. The consolidated analysis is included in the docket for the final rule, but was not available during the public comment period (ICF, 2015a). This document is a consolidated sector-by-sector market characterization for those sectors addressed in this action. While it incorporates some suggestions and information provided by commenters, it otherwise does not add new substantive information other than that provided in the individual market characterizations at the time of the proposed rulemaking. It merely consolidates the information for ease of reference.

We disagree with the comments suggesting that EPA did not consider factors other than GWP. In the NPRM, for each end-use or sector, EPA provided information comparing the alternatives and applying the full set of regulatory criteria, not solely GWPs, in deciding whether to change the status of

a listed substitute, consistent with SNAP's past practices. As one example, in discussing the change in status for HFC–227ea in the aerosol propellant end-use, the Agency explained in the preamble that other available substitutes have zero ODP, are relatively low in toxicity, are capable of remaining below their respective exposure limits, and are expected to have negligible impact on ground-level ozone levels (79 FR 46126, 46173). In each case, consistent with the decision criteria listed at 40 CFR 82.180(a)(7), EPA has considered environmental impacts, flammability, toxicity, and exposure. In the context of this review, we considered a large amount of information including, among other things: Scientific findings, information provided by the Technology and Economic Assessment Panel (TEAP) that supports the Montreal Protocol, journal articles, submissions to the SNAP program, dockets for other EPA rulemakings, presentations and reports presented at domestic and international conferences, and materials from trade associations and professional organizations. References cited in the NPRM were listed in section IX of that document and the references cited in this final action are listed in section IX of this document.

Solvay suggested a number of considerations they believe should have been included as part of EPA's decisionmaking criteria, such as various standards and codes, product shelf-life, and equipment limits. Solvay does not discuss how the various considerations mentioned relate to the existing SNAP review process. In general, we took such considerations into account to the extent relevant to the criteria for review of a substitute or to the availability of other alternatives. For example, we considered such issues as the supply and characteristics of alternatives as well as the status of various regulations and codes and standards as they relate to the availability of the alternatives and thus the appropriate time for the change of status. EPA specifically mentioned building codes (id. at 46143) and energy efficiency and requested comment on "the effect, if any, [the] proposal would have on meeting applicable DOE standards." (id. at 46147). We also noted that plans for the production of an alternative to HFC-134a in the MVAC end-use "are in place to make it available in volumes that meet current and projected domestic auto industry demand." (id. at 46141)

We also addressed certain of these issues in the context of the potential mitigation of risks both for those substitutes subject to the status change and those that remain available. For

example, we noted in the preamble to the NPRM, in the context of alternatives in several of the foams end-uses, that flammability issues would be addressed in the process of meeting OSHA regulations and fire codes (id. at 46,152, 46,153); and in the context of the retail food refrigeration and vending machine end-uses, that exposure limits for the alternatives, including workplace exposure limits of the AIHA and from OSHA and NIOSH, would be met. (id. at 46,144). Concerning other technical concerns such as solubility, compatibility, and shelf stability, this is not information that the SNAP program has routinely requested or received, either for the substitutes used for comparison purposes or for those being evaluated for listing. We have recognized, and when warranted, made changes responding to such technical considerations in this final rule where commenters provided information relevant to the availability of alternatives: For example, in establishing the change of status date for stand-alone refrigeration equipment, we took into consideration that certain larger capacity commercial stand-alone refrigeration equipment requires charge sizes larger than those established in the use conditions for most flammable refrigerants.

Similarly, Mexichem suggested that EPA was required to evaluate specific questions regarding performance, availability, hazard, exposure, and cost. Again, this ignores the established criteria that EPA uses in determining whether a substitute is acceptable or unacceptable in a specified end-use. In the NPRM, in determining whether other substitutes were available that posed lower risk than those for which we proposed to change the status, EPA evaluated the ozone-depletion, climate, local air quality, toxicity and flammability risks of the substitutes undergoing a change of status as well as of other alternatives, thereby addressing hazard and exposure concerns. We note that the statute refers to overall risk to human health and the environment, and does not require that the substitutes be better in terms of each potential human health and environmental concern. EPA does not typically compare the performance or efficacy of substitutes except in considering whether a substitute is technically feasible (see definition of "potentially available" at 40 CFR 82.172). In other words, it is not necessary for EPA to evaluate whether other alternatives perform as well as HFC-134a (or other HFCs) in the specific end-use in order to determine that overall risks to human health and

<sup>&</sup>lt;sup>100</sup> EPA also placed in the docket a document on exposure limits for alternatives in the foam blowing sector, titled, "Information on workplace exposure limits for foam blowing agents."

the environment would be reduced through use of those alternatives.

We have considered whether other alternatives will be available in sufficient quantities as part of our analysis of the availability of alternatives. As discussed in the NPRM, we set dates for the proposed status changes that reflect when there will be a sufficient supply of the alternatives. (id. at 46,141) In some instances, we have revised those dates in this final action after taking into account information on supply of alternatives submitted by commenters.

One of the regulatory criteria for review of a substitute is the "cost and availability of the substitute" (59 FR 13044, Mar. 18, 1994; 40 CFR 82.180(7)(vii)). The consideration of cost under this criterion is limited to the cost of the substitute under review; it is distinct from consideration of costs associated with the use of other alternatives to which the substitute is being compared. See Honeywell, 374 F.3d at 1,378 (J. Rogers, concurring in part and dissenting in part) ("While the SNAP regulations make the 'cost and availability of the substitute' an element of acceptability . . . that concern is limited to whether EPA 'has . . . reason to prohibit its use,' not to whether cleaner alternatives for the substance are already 'currently or potentially available'. . . . Consideration of transition costs is thus precluded by the SNAP regulations as currently written, irrespective of whether it might be permitted under CAA § 612(c). . . . ") Contrary to Solvay's contention, including the cost of the substitute in the list of review criteria does not amount to an acknowledgment that the term "practicable" as used in section 612(a) necessarily involves consideration of the costs associated with using other alternatives. EPA has not determined whether the term "practicable," the term "available," or other terms in section 612 provide discretion to consider such costs. Similarly, our existing regulations do not direct us to consider whether use of the other alternatives involves an equivalent cost to that of HFC-134a or a cost-effective mitigation of CO<sub>2</sub> emissions. We are not addressing in this rulemaking whether to revise the regulatory criteria to include an expanded role for the consideration of costs in SNAP listing decisions. We have simply applied the existing regulatory criteria in determining whether to change the listing status of the substitutes addressed in this action. Thus, we have not considered the costs of transition to other alternatives.

Several commenters suggested or implied that EPA's action was based "excessively" or solely on GWP. As discussed above, we performed a full comparative risk analysis for each of the substitutes and for each end-use for which we are changing the status. However, as noted in the preamble to the NPRM, EPA issued this proposal in response to the CAP. As such, in determining which substitutes and enduses to address in the proposed rule, we evaluated the existing listing decisions in the eight sectors covered by the SNAP program. In three of the sectors, we identified a subset of substitutes that have a high GWP relative to other listed alternatives and for which we also had reason to believe other alternatives were "available" for the end-use. For those substitutes included in the proposed rule on the basis of having a relatively higher GWP, in most cases, EPA did not find significant potential differences in risk with respect to the other criteria, with the exceptions of flammability and local air quality impacts. However, where flammability risk was a potential concern, we concluded that such risk is mitigated by the existing use conditions or through other existing regulations (e.g., OSHA). In the case of spray foam, we proposed to change the status of fewer HFCs than in other foam blowing end-uses in consideration of greater flammability risks in that end-use. Regarding VOC emissions and potential impacts on local air quality, for the aerosol propellant end-use, we did not propose to change the status of HFC-152a, a VOC-exempt aerosol propellant.

## B. Cost and Economic Impacts of Proposed Status Changes

EPA received a number of comments on the cost and economic impacts of the proposed rule. Some of these comments are summarized in the response to comments sections for the end-uses addressed in this final rule. We summarize and respond to the more general cost comments below.

## 1. Costs of Proposed Rule

Comment: EPA received several comments indicating that the commenters believe EPA should provide more time in order to avoid undue burden on the U.S. economy. NAFEM comments that if this rule is finalized as proposed, the change from using R-404A will be very costly. NAFEM stated that compliance cost estimates range from \$500,000 to several million dollars depending on the number and variety of custom products the manufacturer offers. They further comment that testing costs are routinely several hundred thousand dollars and

increase with the variety and level of customization. NAFEM comments that in addition, manufacturers will lose revenues waiting for the limited number of testing facilities able to accommodate the industry's products. The Alliance for Responsible Atmospheric Policy (the Alliance) requests that greater weight be given to economic considerations where the Agency is determining dates for availability of new alternatives, or changing the listing status, which unlike SNAP listing, may require businesses to alter practices and business models. The Alliance also requests that these economic considerations also be undertaken cognizant of competing regulatory initiatives. The Alliance also comments that the SNAP change of status process should be used sparingly, since its economic implications should require a higher scrutiny in considering transition dates and market assumptions than is needed for the SNAP listing approval process. DuPont comments that it is important to reduce emissions in a way that does not slow down global trade, and to achieve emissions reductions in a cost-effective manner. Arkema comments that no SNAP rule should impose unreasonable burdens on the U.S. economy. Arkema believes that EPA must allow more time for transitions to avoid that outcome. Mexichem believes EPA failed to take into account the economic implications of the proposed rule.

Response: As discussed more fully in section VII.A.7, under the SNAP criteria for review in 40 CFR 82.180(a)(7), the only cost information that EPA considers as part of its SNAP review of substitutes is the cost of the substitute under review. The transition timelines in this final rule are based on information concerning the availability of alternatives.

Comment: Arkema commented that EPA underestimated the costs of the NPRM. Arkema believes EPA's cost estimates are unduly optimistic given all that must be done to redesign equipment. Arkema further commented on three areas of economic analysis that they state need to be addressed. First, Arkema stated that EPA does not include the "wasted costs" incurred by those manufacturers that have actually changed designs of their equipment to meet DOE standards, based on the continued availability of existing SNAP substitutes, but that now may need to change their designs again. Second, Arkema suggested that EPA should account for "economic effects" on U.S. plants that produce HFC-134a and the other HFCs and HFC blends whose listing the Agency proposed to change. Third, Arkema suggested that the

economic analyses should disclose how EPA expects prices and availability to change once it eliminates competing products, including stimulation of short-term demand for the HFCs and HFC blends whose listing the Agency proposed to change, longer term increases in prices for the HFCs and HFC blends, and increased demand for next-generation fluorinated products. Solvay commented that given the cumulative regulatory burden, EPA has dramatically underestimated the costs of the NPRM. As an example, Solvay pointed to the DOE energy conservation standards.

Response: Although EPA did not consider the costs of transitioning to other alternatives in making the listing decisions in this rulemaking, we did prepare a cost analysis and a small business impacts analysis for this rule for businesses that are directly regulated.

We do not typically analyze cumulative regulatory burden in our cost analyses. Nonetheless, EPA notes that to the extent that affected entities recently incurred costs to comply with DOE rulemakings, the change of status dates in the final rule for the foam blowing sector and for some of the refrigeration end-uses (e.g., vending machines) may reduce the potential for additional costs due to complying with both rules compared to the change of status dates in the NPRM, since equipment manufacturers should better be able to coordinate DOE's requirements and these SNAP requirements. For example, the change of status date for rigid PU appliance foam is January 1, 2020, while based on the 2014 compliance date of the most recent DOE standards, the compliance date for any revised energy conservation standard for household refrigerators and freezers would be no earlier than 2020. For vending machines, the final change of status date is January 1, 2019, which will likely coincide with compliance requirements for any new or amended DOE refrigerated beverage vending machine standards, as compliance with such standards would be required three vears after the publication of a final rule. Material in the docket for that action indicate DOE's plans for a final rule with a compliance date three years later (see EERE-2013-BT-STD-0022).

Second, EPA has analyzed the costs of users that are directly regulated and has not analyzed the impacts on chemical producers, which are indirectly affected by the regulation. The commenters did not provide specific cost or supply information regarding redesigning equipment or specific information on operating costs for chemical plants that

would have allowed us to analyze the impacts as requested by Arkema. We disagree with Arkema that it is necessary or appropriate to analyze the indirect impacts upon chemical plants and producers. Such analysis would be highly speculative about the degree of cost pass-through from producers to consumers of these chemicals. The total cost estimates would be unchanged; rather such an analysis would relate to transfers between producers of the substitutes undergoing a change of status, producers of the acceptable alternatives for the same uses, and consumers of these products rather than losses to the economy or to a market sector as a whole. We note that the transition affecting the majority of HFC-134a production, the transition away from HFC-134a in MVAC, is already occurring because of other regulations, and therefore changes to production and cost of HFC-134a cannot easily be attributed to this action.

EPA recognizes that transitioning to other alternatives is likely to require capital costs and investments in research, updated equipment, and their related financial impacts. Many chemical producers have either submitted SNAP notifications or expressed interest in submitting SNAP notifications concerning new molecules and blends of existing molecules. EPA agrees with Arkema that this rule is likely to stimulate demand in next-generation alternatives further.

EPA also notes that, for example, HFC–134a likely will be a component of many low-GWP blends that are being developed specifically to replace HFC–134a. EPA listed as acceptable one of those blends, R–450A, on October 21, 2014 at 79 FR 62863. The Agency is aware of additional blends that multiple chemical producers are developing. As noted throughout this document, the range of alternatives includes new molecules and existing compounds, encompassing fluorinated, nonfluorinated and in some cases not-in-kind alternatives.

Third, we question Arkema's assumption that competition will decrease and thus cost for low-GWP alternatives will rise. For each of the status changes in this final action, more than one other alternative is currently listed as acceptable or acceptable, subject to use conditions, for the relevant end-use. Moreover, we expect new SNAP submissions that would result in the introduction of further alternatives to increase, rather than reduce, competition. Further, because this rule does not regulate production of individual chemicals directly and allows servicing of existing refrigeration

and AC equipment with the refrigerants for which they are designed, we expect there will continue to be a market for HFC–134a and other HFC refrigerants for years to come.

In those cases where commenters provided specific, detailed cost information, we used that information to revise the cost assumptions in our updated cost analysis for this final rule. For additional information on economic analysis conducted for this rule, see the supporting document "Revised Cost Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives" (ICF, 2015c).

Comment: NRDC and IGSD commented that the rule is important because it provides a needed signal to various industrial sectors that as safer alternatives are brought to market, substitutes with high GWPs will be removed from the SNAP list. NRDC and IGSD commented that this provides American companies with an opportunity to become industry leaders as the global market moves away from high-GWP substances, by developing new chemicals and processes to transition the refrigeration, cooling, aerosol and foams markets as quickly as possible. NRDC further commented that this rule will establish U.S. industry as a leader in safer chemicals, helping pave the way for global action under the Montreal Protocol. NRDC noted that when EPA previously proposed phasing down CFCs and ODS, there were warnings about dire impacts on industry that did not come to pass, and NRDC expects this will be true for this rule as well. NRDC commented that 25 years of experience with the Montreal Protocol and the CAA has shown us that transitioning to safer chemicals works smoothly.

Response: EPA appreciates this comment and agrees that there are many innovative U.S. companies bringing new low-GWP, energy-efficient products to market.

2. EPA's Cost Analysis and Small Business Impacts Screening Analysis

Comment: EPA received a number of comments indicating that small businesses bear a disproportionate share of the regulatory burden and that the NPRM represents a "significant regulatory action," NAFEM comments that EPA must conduct a complete analysis of the impacts on small entities before any final regulation can be promulgated. NAFEM comments that EPA's analysis is too narrow, is incomplete, and that its conclusions are unsupported. NAFEM further comments that the NPRM disproportionately affects small entities. NAFEM comments

that the NPRM represents a major rule and will have a \$100 million effect on the economy and a major impact on the commercial refrigeration industry and its consumers. NAFEM commented that the docket lacks a robust industry analysis of the effects on small business manufacturers and customers, or reasonable support for EPA's Regulatory Flexibility Act conclusions. NAFEM recommends that EPA initiate a Small **Business Regulatory Enforcement** Fairness Act (SBREFA) Small Entity Representative review panel to help inform final rulemaking, as required by the Regulatory Flexibility Act. Solvay also commented that EPA should convene a Small Business Advocacy Review Panel under the SBREFA.

Response: E.O. 12866 states that rules that have an impact on the economy of \$100 million per year qualify as significant regulatory actions. EPA disagrees that this rule would have an impact on the economy of \$100 million more per year. We performed an analysis of the costs of the proposed rule on businesses and estimated the total annualized upfront compliance costs to range from \$8.9 million to \$41.6 million; total annual savings are estimated to be about \$25.1 million (ICF, 2014g). This cost analysis did not evaluate the share of costs likely to be borne by consumers, since it is not clear what proportion of cost impacts may be carried on to consumers, and further, such economic analyses typically look at costs to the regulated community rather than indirect impacts on consumers. We updated this analysis based upon the regulatory options and change of status dates in the final rule, and using cost information provided by commenters. The changes in the final rule—especially with respect to compliance dates—reduce the cost impacts on small businesses, while the updated cost information resulted in higher cost estimates. In this updated analysis, we estimated the total annualized upfront compliance costs to range from \$28.0 million to \$50.6 million, using a 7% discount rate, and from \$19.5 million to \$37.8 million, using a 3% discount rate. Total annual savings are estimated to be about \$19.3 million (ICF, 2015c). In either case, this is well below the \$100 million per year threshold to consider this an economically significant rule on economic grounds.

EPA disagrees with the commenter that the "docket lacks a robust industry analysis on the effects on small business manufacturers and customers, or reasonable support for EPA's Regulatory Flexibility Act conclusions." The Agency's screening analysis at proposal

stage is included in the docket (ICF, 2014f). The commenters do not point to any specific aspect of that analysis that they believe are deficient. A Small Business Advocacy Panel is convened when a proposed rulemaking is expected to have a significant impact on a substantial number of small entities, or "SISNOSE." We have updated our small business impacts screening analysis using the change of status decisions and dates in the final rule, adding boat manufacturers as affected entities, and using detailed cost information provided by commenters (ICF, 2015b). EPA's preliminary and final screening analyses concluded that this rulemaking would not pose a SISNOSE. In the analyses, EPA recognized that some small businesses may experience significant costs, but concluded that the number of small businesses that would experience significant costs was not substantial.

Both the screening analysis for purposes of determining whether there was a SISNOSE and the analysis to determine whether the rule was significant based upon economic grounds were conducted based on the best market and cost information available to the Agency. Where commenters provided specific market or cost information, the Agency used that information to update these analyses. The updated analyses came to the same conclusions: That the final rule would not pose a SISNOSE and that it is not an economically significant rule (ICF, 2015b,c).

# C. Environmental Effects of Proposed Status Changes

EPA received submissions from 42 commenters related to the environmental impacts of the proposed status changes. Additionally, EPA received 7,022 mass mailing letters commenting on the importance of transitioning away from HFCs to more climate-friendly alternatives. Ten commenters referred to the CAP.

#### 1. General Comments

Comment: EPA received over 7,000 substantially identical comments regarding the climate impacts of HFCs and supporting action to address the growth in usage of these potent greenhouse gases. The commenters also stated that that the rest of the world, including Europe and Japan, is taking action to reduce HFC emissions, so the United States should also transition away from HFCs to protect the planet from the catastrophic impacts of climate change. They also stated that it is of the utmost importance to limit "superpotent" greenhouse gases from use in

refrigerators, air conditioners, aerosols and foams and substitute them with safer, more climate-friendly alternatives. They also noted that some HFCs remain in the atmosphere for decades or even centuries after they are released, so that they have a strong cumulative effect. NRDC stated that if EPA were only considering human health risks, HFCs should be banned immediately given the climate risks. NRDC commented that we know these chemicals are extremely potent agents of climate change, and we know that continuing to use them only exacerbates the climate problem. EIA requested that EPA continue to remove high GWP HFCs from the lists of acceptable substitutes, given that HFC emissions are set to double by 2020 and triple by 2030, and given that this rule has the potential to reduce 42 MMTCO<sub>2</sub>eq by 2020. EIA urged EPA to address all sectors covered in the SNAP program, given the needs of climate and the existence of climate-friendly alternatives. DuPont commented that they acknowledge the environmental need to avoid future growth in GHG emissions, and have thus developed low-GWP, energy efficient products.

Response: The Agency appreciates the support of actions to list change the status of certain HFCs. Other actions urged by the commenters are outside the scope of this rulemaking.

#### 2. EPA's Benefits Analysis

Comment: EPA received a number of comments regarding the importance, significance, and magnitude of the environmental benefits of avoided HFC emissions that would result based on the proposed rule.

CARB comments the current regulations and the SNAP proposal meet only half of the 80% reduction necessary for the HFC sector if California is to meet its overall GHG reduction goal contained in California Executive Order (EO) S–3–05 (2005). Therefore, CARB believes additional HFC reductions are required to reduce this fastest-growing source of GHGs.

NRDC and IGSD comment that even though HFCs may currently make up a small piece of global climate emissions, their projected rapid growth underscores the urgent need to replace these chemicals with lower-GWP alternatives. Further, NRDC and IGSD comment that without stringent rules in place, HFC emissions increases could counteract the progress EPA is striving to make in other sectors to reduce carbon pollution.

Response: EPA appreciates the support for reducing GHG emissions, and appreciates the estimates of the benefits in terms of MMTCO<sub>2</sub>eq that the

commenters provide. CARB's comment concerning meeting GHG reduction goals in a California EO are beyond the scope of this rule; we may consider additional status changes in a future rule. We agree with NRDC and IGSD that HFC emissions are growing rapidly and that it is timely to act now to encourage use of lower-GWP alternatives and ensure continuing progress. The Agency notes that both EPA's estimates cited in the NPRM and the estimates the commenters provide are based on the provisions of the proposed rule, and that the benefits from this final rule differ. For further information, see EPA, 2014 and EPA,

Comment: Arkema comments that at this time, it is not possible to provide a more detailed critique of the Vintaging Model's assumptions and the levels of sector emissions given the lack of meaningful information in the docket. Arkema comments that the docket does not provide all the model inputs, nor does EPA disclose the specific emission factors that it used to derive its estimates, how recent those estimates are, and how they are expected to change over time. Arkema comments that EPA's benefits analysis nowhere details the extent of the uncertainties in its emissions estimates, even though the record elsewhere acknowledges that such emissions estimates may be unreliable.

Response: As an initial matter, EPA did not rely on the Vintaging Model in reaching decisions about whether other alternatives present lower overall risk. Nor did EPA otherwise rely on the benefits analysis that accompanied the proposed rule. We estimated emissions reductions resulting from this rulemaking in order to provide information to the public. Consistent with section 612(c) of the CAA, EPA relied on the criteria for review specified in the SNAP regulations at 40 CFR 82.180(a)(7) in determining whether the substitutes for which we proposed to change the status presented greater risk to human health and the environment than other available

As part of the process for listing alternatives, EPA evaluates information concerning a substitute according to the criteria in EPA's regulations at 82.180(a)(7) (e.g., atmospheric effects, ecosystem risks, occupational and consumer risks, availability) in comparison with other available substitutes for the same end-uses. At the time of review, we prepare a risk screen and place it in the relevant public docket for our listing decisions. It is rare for risk screens to include information

from the Vintaging Model, although such information may be used in some cases to estimate emissions (e.g., VOC emissions from an end-use where the submitter has provided insufficient information). The preambles to this final rule and the NPRM include information summarizing the comparisons to other alternatives. In addition, we also have docketed a document which provides the **Federal Register** citations for the information on the health and environmental characteristics of various alternatives in the end-uses covered in this final rule (EPA, 2015d).

See the next response for further information about where one can find information on the modeling assumptions and methodology.

Comment: Arkema commented that in order to calculate HFC sector emission savings, the Vintaging Model needs to be revised since it is over-estimating chemical demand. Arkema also commented that the basis and methodology for the Vintaging Model's emissions estimates are unclear, but a comparison to publicly available information should have raised red flags because a steady growth rate of HFC emissions in the U.S. is extremely unlikely for at least three of the four covered sectors (i.e., MVAC, aerosols, and foams). For MVAC, Arkema comments that refrigerant charge sizes have been dropping, and new cars will be transitioning to low-GWP alternatives over time. Arkema notes that for aerosols, a significant portion of the aerosol product manufacturing industry has already transitioned out of the HFCs proposed for regulation. In addition, Arkema points out that UNEP's 2014 TEAP report shows that hydrocarbon technologies already dominate the foam sector.

Response: EPA's Vintaging Model has been explained annually in the Inventory of U.S. Greenhouse Gases and Sinks 101 report and other places. For example, the 2015 annual Inventory of U.S. Greenhouse Gas Emissions and Sinks report, EPA Report 430-R-15-004 (EPA, 2015c), covers emissions, including emissions of HFCs used as ODS alternatives, for the years 1990 through 2013 and provides in detail the basis and methodologies used. The commenter is misinformed with respect to the assumptions used in the model. Specifically, the model does assume that MVAC refrigerant charge sizes have dropped over time, and it utilizes detailed sector information to calculate such changes. In addition, it does

assume that a significant portion of the aerosol product manufacturing industry has transitioned out of HFCs. Although the cited 2014 TEAP report—which the commenter states indicates hydrocarbon technologies dominate the foam sector—applies globally rather than specifically to the United States, EPA notes that its Vintaging Model does specifically assume that significant transition in the foam industry to non-ozone-depleting, low-GWP substances, including hydrocarbons, has occurred.

Comment: Arkema comments that as far as they are aware, EPA has never submitted its Vintaging Model for external peer review. Arkema comments that the Vintaging Model qualifies under the Agency's Peer Review Handbook as "influential scientific information" for which external peer review is warranted. Arkema believes that the underlying data has been kept a secret. Arkema comments that EPA's NPRM is not consistent with Administrator McCarthy's three pillars of EPA's scientific conclusions: Transparency, rigorous peer review, and robust, meaningful public comment. Arkema comments that EPA cannot obtain robust, meaningful comments if the Vintaging Model is not subject to peer review and if underlying data is kept secret.

Response: As explained above, EPA used its Vintaging Model to provide information to the public, but does not rely on that information to support today's rule. Thus, the issue of whether the Vintaging Model should be subject to a peer review process is outside the scope of this rulemaking action.

#### 3. Energy Efficiency

Comment: EPA received a number of comments regarding energy efficiency and LCCP of refrigeration equipment. NAFEM commented that the life-cycle climate performances of manufacturers show that only about 10% of the environmental impact is due to a combination of refrigerant leak, charge amount and GWP of the refrigerant; the rest relates to energy efficiency. NAFEM asserted that the proposed SNAP rule does not account for nor can EPA claim any significant environmental benefits to offset significant costs. The Alliance noted that given the important energy efficiency consequences of this proposed rule, it is unclear how this action will meet the statutory standard of no greater risk to human health and the environment. The Alliance commented that by taking previously acceptable substitutes off the market, these proposals could result in less efficiency in the near term. The Alliance further comments as EPA evaluates the

<sup>&</sup>lt;sup>101</sup> Available online at www.epa.gov/ climatechange/ghgemissions/usinventoryreport/ 2014 html

timing of transitions in various end-use segments, it is important that life cycle greenhouse gas emissions, including those associated with energy use, are given proper consideration as part of ensuring the alternative presents "no greater risk to human health and the environment."

Response: EPA provided estimates of the climate benefits associated with the NPRM, and we have also estimated the climate benefits associated with this final rule (EPA, 2014; EPA, 2015b). These estimates are based on avoided direct HFC emissions. They are distinct from our evaluation of whether other alternatives are currently or potentially available that present less overall risk to human health and the environment. EPA does not have a practice in the SNAP program of including indirect climate impacts or energy efficiency in the overall risk analysis. We do consider issues such as technical needs for energy efficiency (e.g., to meet DOE standards) in determining whether alternatives are "available." Elsewhere in this final action, EPA addressed and responded to comments concerning energy efficiency (see in particular sections V.C.3.c, V.C.4.c, V.C.7 and V.D.3.c). EPA notes that the refrigerant is only one of many factors affecting energy efficiency. Moreover, even as refrigerant transitions have taken place over past decades, we have seen improved energy efficiency. This is often due to equipment redesigns and technology advancements that include factors besides the choice of refrigerant. EPA notes that a number of models are already commercially available that do not use the refrigerants subject to a change of status in this final rule and also meet or exceed the relevant energy conservation standards and thus reduce both direct and indirect climate impacts.

#### 4. The Climate Action Plan

Comment: EPA received six comments commending the EPA for quickly proposing a rule to achieve the goals in the President's CAP.

Response: EPA appreciates the support from this wide variety of interested stakeholders on addressing the goals in the President's CAP.

Comment: EPA received two comments questioning whether the President's CAP provides authority to regulate HFCs.

Response: Section 612 of the CAA, not the CAP, provides the authority for this action. CAA section 612(c) requires EPA to list a substitute as unacceptable if other available alternatives pose lower risk to human health and the environment.

Comment: Two comments stated that EPA's response to the President's CAP in the NPRM did not consider full ramifications of the challenges to industry.

Response: The NPRM proposed changes to listings based on the information the Agency had at the time of the proposal. We requested comments to further our understanding of any potential challenges relating to technical feasibility or supply. We considered that additional information as we developed the final rule.

## D. Potential Exemptions

Comment: EIA commented on potential exemptions, specifically the need for a mechanism to petition for an essential use exemption or for more time with a valid basis. The commenter recognized that the potential for the misuse of such a mechanism could overwhelm the resources of the EPA available for this transition. As a result, EIA recommended that EPA grant no blanket exemptions or delays due to the needs of one or a few sectors but that EPA establish an exemption mechanism with a penalty clause to avoid misuse.

Response: The SNAP regulations do not currently contain an across-theboard mechanism for petitioning for an exemption, and EPA did not propose such a mechanism in the NPRM. To make such a change in our regulations, we would first need to provide an opportunity for public comments. In some instances in the final rule EPA has changed a listing to acceptable, subject to narrowed use limits. The narrowed use limits identify a narrow part of the end-use in which an end user could use an otherwise unacceptable substitute if they can support that no other acceptable substitutes are available for their specific application.

#### E. Interactions With Other Rules

Comment: The Alliance, AHAM, AHRI, and a number of other commenters in the commercial refrigeration and home appliance industries expressed concern about the feasibility of using other alternatives to meet DOE energy conservation standards. AHRI and Coca-Cola stated that DOE's federal minimum energy conservation standards are based on refrigerants and foam blowing agents that EPA is now proposing to list as unacceptable. NAFEM comments that manufacturers are now finding that developing a product to meet both the energy conservation standards and also utilizes acceptable alternative refrigerants and blowing agents is daunting if not impossible. Commenters pointed out that they have redesigned

products to meet DOE energy conservation standards due to take effect in 2017. See section V.C.1.b for a discussion of DOE energy conservation standards that apply to the equipment affected by this rule.

Response: Given that today's rule contains later deadlines than proposed, as well as a phased-in approach with different status change dates for different kinds of equipment as suggested by many commenters, this should address commenters' concern about meeting both sets of requirements. 102 EPA continues to coordinate with DOE as EPA reviews alternative refrigerants and foam blowing agents, DOE tests energy efficiency of certain alternative refrigerants, and the two agencies discuss each other's rulemakings in development. EPA sees the redesign of products as an integral part of business operations, and believes redesigning equipment to use refrigerants that pose a lower overall risk to human health and the environment is in many ways similar to past redesigns. We believe that manufacturers can incorporate lower-GWP refrigerants in stand-alone retail food refrigeration equipment and remote condensing units while designing for DOE energy conservation standards for commercial refrigeration equipment and for walk-in coolers and freezers, both of which have compliance dates in 2017, and can incorporate lower-GWP foam blowing agents while designing for DOE standards for household refrigerators/freezers. Based on the 2014 compliance date of the most recent DOE standards for residential refrigerators and freezers, the compliance date for any revised energy conservation standard for household refrigerators and freezers would be no earlier than 2020. As discussed in the previous and following responses and in sections V.C.7 and V.D.3.c) as well as other sections of this preamble, there are both refrigerants and foam blowing agents with lower GWPs available that allow for improved energy efficiency compared to the substitutes we are finding unacceptable in this rule. EPA anticipates that innovative companies

<sup>102</sup> If a manufacturer believes that its design is subjected to undue hardship by DOE's regulations, the manufacturer may petition DOE's Office of Hearing and Appeals (OHA) for exception relief or exemption from the standard pursuant to OHA's authority under section 504 of the DOE Organization Act (42 U.S.C. 7194), as implemented at subpart B of 10 CFR part 1003. OHA has the authority to grant such relief on a case-by-case basis if it determines that a manufacturer has demonstrated that meeting the standard would cause hardship, inequity, or unfair distribution of burdens.

will seize this opportunity to develop more efficient and profitable designs.

Comment: A number of manufacturers of commercial refrigeration products commented on the relative energy efficiency of alternative refrigerants, compared to the refrigerants proposed to be unacceptable. Lennox commented that the substitution of R-407 family refrigerants in place of R-404A and R-507A will negatively affect the efficiency performance of refrigeration equipment for walk-in coolers and freezers. Structural Concepts stated that switching from R-404A to R-744, and consequently switching to thicker piping and new compressors, would increase energy usage overall by 45%; which would cause the unit to exceed the allowable energy level determined by the DOE. AMS commented that after studying the suitability of the acceptable (R-744) and proposed acceptable (R-290, R-600a and R-441A) alternatives extensively, it concluded that only R-290 will allow it to meet DOE energy conservation mandates. NAMA stated that because of DOE requirements, CO2's use would be limited to indoor selfcontained units, limiting locations of refrigerated vending machines, reducing revenues for the entire supply chain and reducing consumer choice. Information in the Agency's possession describes a manufacturer's testing of the energy efficiency of condensing units with R-404A compared to R-407A, finding that the energy efficiency was typically higher with R-407A in mediumtemperature equipment but was typically lower with R-407A in lowtemperature equipment (EPA-HQ-OAR-2014-1098-0184). Structural Concepts comments that R-744 is not flammable, but it is less energy efficient than the acceptable, flammable refrigerant propane, and to meet the EPA proposed regulation would likely mean they fail to meet DOE regulations or go out of business trying to meet them.

Response: EPA expects that no single refrigerant will improve energy efficiency compared to the unacceptable refrigerants in every type of equipment or in every situation. For example, the information regarding a manufacturer's test results indicates that R-407A may provide improved energy efficiency compared to R-404A for mediumtemperature refrigeration equipment (refrigerators), but not necessarily for low-temperature refrigeration equipment (freezers); this information indicates that Lenox's comment about lower energy efficiency of R-407A compared to R-404A or R-507A may be correct for low-temperature equipment and incorrect for medium-temperature

equipment. We agree with the commenters who noted that R-744 may be more energy efficient in locations with lower ambient temperatures and thus may be more suitable for use indoors than outdoors. R-290 may provide better energy efficiency than HFC refrigerants in many situations, but not necessarily all, and not all end users will want to use a flammable refrigerant. In response to the comment from Structural Concepts expressing concern about the ability to meeting energy conservation standards using CO<sub>2</sub> and the cost of using propane, we note that there are additional refrigerant choices available for stand-alone refrigeration equipment and vending machines besides CO<sub>2</sub> and hydrocarbon refrigerants, such as the nonflammable refrigerants R-448A, R-449A, R-450A and R-513A. As discussed in section V.C.7, these blends may show improved energy efficiency over HFC-134a and R-404A. In addition, design and operation of refrigeration equipment affects energy efficiency and not just the refrigerant used. Given the variety of currently or potentially available alternatives, EPA believes it is unlikely that manufacturers will have to use refrigerants that will result in reduced energy efficiency compared to the refrigerants being listed as unacceptable or otherwise restricted in this final rule, and we expect that manufacturers will be able to meet DOE energy conservation standards with the remaining available alternatives.

Comment: Some manufacturers of commercial refrigeration products commented on how design changes needed to accommodate alternative refrigerants may negatively affect energy efficiency. Parker Hannifin stated that most of the alternatives result in higher discharge temperatures and that some of the discharge temperature control methods employed negatively affect system efficiency. Nor-Lake and Structural Concepts indicated that they expected to need dual compressor systems, and stated that the increased energy usage of the dual system may outweigh the environmental gains of using the alternate lower-GWP refrigerant.

Response: EPA agrees that some design changes could have negative impacts on energy efficiency if they were done without broader considerations for the overall performance of the appliance. As stated elsewhere, many models that comply with DOE energy conservation standards are already commercially available that do not use the refrigerants subject to a change of status in this final rule. We agree with Nor-Lake and

Structural Concepts that dual compressor systems are more likely needed for larger equipment, particularly larger equipment using hydrocarbon refrigerants which have use limits restricting the refrigerant charge in a single refrigeration circuit. Recent listings of additional nonflammable refrigerants (e.g., R-450A) allow for additional options that would not require dual compressors. In response to Parker Hannifin's comment about discharge temperatures, we note that producers of some alternative refrigerant blends under review by the SNAP program claim that these new blends have operating properties similar to those of HFC refrigerants, such as similar operating pressures and discharge temperatures.

Given the variety of currently or potentially available alternatives, EPA believes it is unlikely that manufacturers will have to use refrigerants that will result in reduced energy efficiency compared to the refrigerants being listed unacceptable in this final rule.

Comment: The Alliance, AHAM, AHRI, and a number of other commenters in the commercial refrigeration and home appliance industries suggested that the SNAP rulemaking schedule should be better coordinated with the ongoing DOE energy conservation standard rulemaking schedules. AHAM comments that firms have invested millions of dollars to meet new DOE conservation standards that were based on the assumption of the availability of HFCs, and have diverted the scarce capital that is available for regulationdriven investment. The National Association of Manufacturers (NAM) requested that the EPA harmonize the rule with the DOE rule in order to ease the capital- and design-intensive manufacturer transition. Scotsman Ice Systems and Whirlpool Corporation stated that as a result of the potential regulatory measures, their ability to develop any customer focused products or new product features during this time will be constrained. GE Appliances notes that the burden of overlapping regulatory requirements between SNAP and the DOE require consideration and review under the executive orders issued by President Obama and his predecessors that require consideration of cumulative regulatory burden.

Response: EPA's timeframes are based upon our understanding of the availability of alternatives, considering technical challenges and supply. The timeframes in this final rule take into account additional information on availability provided to the Agency

during the comment period. These timeframes account for the time needed to meet the technical challenge of designing equipment using alternative refrigerants that can meet the DOE requirements. We note that EPA and DOE coordinate to the extent possible. For example, each agency has reviewed the other's rules. The list of acceptable SNAP alternatives is evolving. EPA is also coordinating with DOE to ensure more alternative refrigerants are being tested for energy efficiency. We recognize that as manufacturers focus on designing equipment to meet the DOE standards and to use refrigerants acceptable under the SNAP program, they may need to divert design resources from other projects for that period of time. However, as provided in section VII.A.7, this type of transition cost is not a part of the SNAP review criteria. As explained in the Statutory and Executive Order sections at the end of the NPRM and of this final rule, EPA has complied with those requirements.

Comment: The National Restaurant Association (NRA) comments that the food industry is already being affected by the EPA's rule Listing of Substitutes for Refrigeration and Air Conditioning and Revision of the Venting Prohibition for Certain Refrigerant Substitutes. NRA believes the EPA should consider the impacts of the cumulative regulatory burden of rulemakings and standards imposed nearly simultaneously on manufacturers of this equipment in the final rulemaking.

Response: The rule entitled "Listing of Substitutes for Refrigeration and Air Conditioning and Revision of the Venting Prohibition for Certain Refrigerant Substitutes" lists additional substitutes as acceptable, subject to use conditions. It does not mandate use of the newly listed substitutes. Thus, it is unclear how it might result in cumulative regulatory burden together with this rule. Equipment designed using the refrigerants in that rule is not affected by this rule, which concerns different refrigerants. Finally, that rule also has an exemption from requirements under section 608 of the CAA that will reduce regulatory burden.

Comment: Danfoss commented that several of the refrigerants listed as acceptable in the rule titled Listing of Substitutes for Refrigeration and Air Conditioning and Revision of the Venting Prohibition for Certain Refrigerant Substitutes are severely restricted by building codes and would not be acceptable for use in most areas of the U.S, mainly due to their flammability. Danfoss stated they believe that the proposed replacement refrigerants are not able to be used as

short term alternatives to those being found unacceptable because changes to model building codes and subsequent adoption by states and localities will likely be much later than 2020.

Response: EPA acknowledges that some building codes may currently restrict or prohibit use of flammable refrigerants. We note that other available or potentially available refrigerants that are not flammable and have relatively low GWP (roughly 600 or less), including R–744 and R–450A, are listed as acceptable for use in retail food refrigeration and in vending machines.

Comment: A number of manufacturers of laboratory refrigeration equipment and several foam manufacturers suggested that EPA align the timelines for transition of foam blowing agents and refrigerants with the requirements of the EU F-Gas regulations. The commenters summarized the deadlines for foams as: 2008 for one-component foams, January 1, 2020, for XPS, January 1, 2023, for other foams, and provisions for a four-year extension of time where (1) "alternatives are not available or cannot be used for technical or safety reasons" or (2) "the use of technically feasible and safe alternatives would entail disproportionate costs.' Commenters summarized the deadlines for refrigerants in commercial refrigerators and freezers as being January 1, 2020, for HFCs with GWP of 2,500 and January 1, 2022, for HFCs with GWP of 150 or more.

Reasons given for this coordination of timeline with EU regulations include: Many companies are trans-national and had already been planning on a transition in line with the EU regulatory deadlines; the SNAP program has deferred to other regulations in the past; and the later deadlines will allow for redesign of refrigeration equipment for both alternative, flammable refrigerants and for new foam blowing agents and for needed third-party testing. Commenters stated that the proposed deadlines would create an extreme burden, particularly on small businesses; that part supplies needed for compliance are not offered in the United States; and that the transition is a complicated undertaking that cannot be performed in 18 months.

Response: EPA disagrees that it should align the timelines in this rule with the EU timelines. The EU regulations are based upon different authority from the SNAP program and we must decide upon timelines based upon the availability of alternatives in the United States. Concerning the suggestion that EPA has deferred to other regulations, we note that there are several key differences. As an initial

matter, we have deferred to U.S. regulations. More importantly, we have not deferred to other regulations in a manner that overrides the statutory mandate governing the SNAP program. Rather, in the context evaluating risks of alternatives under our comparative risk framework we have looked to regulations in effect, such as workplace regulations from OSHA or the National Emission Standards for Hazardous Air Pollutants, to determine whether a specific alternative may be used as safely as other available alternatives. This is different from aligning with a timeline in another nation's regulations that are not effective within the United States or deferring to considerations in those regulations, such as transition costs, that are not part of the SNAP decision criteria.

#### F. Other Comments

Additional public comments not already discussed above along with EPA's responses are available in the Response to Comments document which accompanies this action (EPA, 2015a).

## VIII. Additional Analyses

EPA does not consider the cost of transition to other alternatives in making listing decisions because under the SNAP criteria for review in 40 CFR 82.180(a)(7), consideration of cost is limited to cost of the substitute under review. However, EPA has prepared technical support documents including analyses of costs associated with sector transitions, estimated avoided GHG emissions associated with the transition to alternatives, and potential small business impacts. 103 104 105

The transition scenarios analyzed possible ways to comply with the final rule. The transition scenario in the cost analysis reflects a direct compliance cost method and does not assume the regulated community chooses highercost solutions where known less costly solutions exist. The scenarios analyzed in the avoided GHG emissions analysis reflect possible transitions for compliance based on considerations of the market and activity towards lower-GWP solutions. While the emission reductions have been quantified, they have not been monetized. Thus, higher or lower GHG emission reductions do

 $<sup>^{103}</sup>$  ICF, 2015a. Revised Cost Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives. July 2015.

<sup>&</sup>lt;sup>104</sup> ICF, 2015b. Economic Impact Screening Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives—Revised. July 2015.

 $<sup>^{105}\,\</sup>mathrm{EPA},\,2015.$  Climate Benefits of the SNAP Program Status Change Rule, July 2015.

not necessarily correlate to higher or lower costs due to the different assumptions and methodologies used in the different analyses. However, the transitions assumed in the lower, less aggressive scenario here are similar to the transitions assumed in the cost analysis.

To extend the assessment to all-sized businesses potentially affected by the rulemaking, EPA conducted an analysis on costs to all-sized businesses building on the approach taken to estimate potential economic impacts on small businesses. Using a 7% discount rate, total annualized compliance costs across affected businesses are estimated to range from \$28.0 million to \$50.6 million; total annual savings are estimated to be about \$19.3 million. Using a 3% discount rate, total annualized compliance costs across affected businesses are estimated to range from \$19.5 million to \$37.8 million, total annual savings are estimated be about \$19.3 million.

EPA conducted an analysis on the potential avoided GHG emissions associated with implementation of this final rule. The emissions avoided from this final rule are estimated to be 26 to 31 MMTCO $_2$ eq in 2020. The avoided emissions are estimated to be 54 to 64 MMTCO $_2$ eq in 2025 and 78 to 101 MMTCO $_2$ eq in 2030 (EPA, 2015b) .

## IX. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at www2.epa.gov/laws-regulations/laws-and-executive-orders.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

## B. Paperwork Reduction Act

This action does not impose any new information collection burden. OMB has previously approved the information collection requirements contained in the existing regulations and has assigned OMB control number 2060–0226. This final rule contains no new requirements for reporting or recordkeeping.

## C. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities. The requirements of this final rule with

respect to HFCs, will impact manufacturers of some consumer and technical aerosol products, retail food refrigeration equipment, vending machines, motor vehicles, and products containing phenolic, polyisocyanurate, polyolefin, PU, and polystyrene foams. The requirements of this final rule with respect to HCFCs could theoretically affect manufacturers of aerosols, foams, industrial cleaning solvents, fire suppressants, and adhesives, coatings, and inks; however, due to existing regulations that restrict the use of HCFCs in these products, no actual impact is expected. In some uses, there is no significant impact of the final rule because the substitutes proposed to be prohibited are not widely used (e.g., use of HFC-134a as a propellant in consumer aerosol products, use of HFC-134a as a foam blowing agent in various polyurethane foams). A significant portion of the businesses regulated under this rule are not small businesses (e.g., car manufacturers, appliance manufacturers). About 500,000 small businesses could be subject to the rule, although more than 99% of those businesses are expected to experience zero compliance costs because other available substitutes for supermarket refrigeration systems and condensing units have costs similar to those of the refrigerants listed as unacceptable. For those small businesses with compliance costs, impacts are estimated to range from 0% to 48% of annual sales, with approximately 57 businesses expected to experience an impact of 3.0% of annual sales or more. Details of this analysis are presented in the document, Economic Impact Screening Analysis for Regulatory Changes to the Listing Status of High-GWP Alternatives—Revised (ICF, 2015b). In our analysis, we found that while some small businesses may experience significant costs, the number of small businesses that would experience significant costs is not substantial. We have therefore concluded that this action will not have a significant impact on a substantial number of small entities.

## D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

#### E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the

relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

#### F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in EO 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

## G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in EO 12866, and because the environmental health or safety risks addressed by this action do not present a disproportionate risk to children. This action restricts the use of certain substitutes that have greater overall risks for human health and the environment, primarily due to their high global warming potential. The reduction in GHG emissions would provide climate benefits for all people, including benefits for children and future generations.

## H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined in Executive Order 13211, (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Aerosol uses are not related to the supply, distribution, or use of energy. For the end-uses that are related to energy effects, including refrigeration and air conditioning and some rigid cell PU and polystyrene insulation foams, a number of alternatives are available to replace those refrigerants and foam blowing agents that are listed as unacceptable in this action; many of the alternatives are as energy-efficient or more energyefficient than the substitutes being listed as unacceptable. As described in more detail in this document, energy efficiency is influenced, but not determined, by the refrigerant. Similarly, although foam blowing agents influence the insulation properties of rigid cell foams, this also can vary due

to other properties of the foam (e.g., thickness). Thus, we have concluded that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

This action does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. This action would prohibit a number of substances with ODPs or high GWPs. The reduction in ODS and GWP emissions would assist in restoring the stratospheric ozone layer and provide climate benefits.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

#### X. References

This preamble references the following documents, which are also in the Air Docket at the address listed in section I.B.1. Unless specified otherwise, all documents are available electronically through the Federal Docket Management System, Docket #EPA-HQ-OAR-2014-0198.

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#### List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Recycling, Reporting and recordkeeping requirements, Stratospheric ozone layer.

Dated: July 2, 2015.

## Gina McCarthy,

Administrator.

For the reasons stated in the preamble, 40 CFR part 82 is amended as follows:

# PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

**Authority:** 42 U.S.C. 7414, 7601, 7671–7671q.

# **Subpart G—Significant New Alternatives Policy Program**

- 2. Appendix B to subpart G of part 82 is amended as follows:
- a. By removing the first entry and adding four entries in its place in the table titled "Refrigerants—Acceptable Subject to Use Conditions".
- b. By adding a new entry at the bottom of the table "Refrigerants—Acceptable Subject to Narrowed Use Limits".
- c. By adding three new entries at the end of the table titled "Refrigerants—Unacceptable Substitutes".

The revisions and additions read as follows:

Appendix B to Subpart G of Part 82— Substitutes Subject to Use Restrictions and Unacceptable Substitutes

#### REFRIGERANTS—ACCEPTABLE SUBJECT TO USE CONDITIONS

Application	Substitute	Decision	Conditions	Comments
CFC–12 Automobile Motor Vehicle Air Conditioning (New Equipment/NIKs only).	HFC-134a	Acceptable subject to use conditions, for passenger cars and light-duty trucks manufactured for Model Year 2020 or earlier, and for vehicles other than passenger cars or light-duty trucks.	must be used with unique fittings.     must be used with detailed labels.	EPA is concerned that the existence of several substitutes in this end-use may increase the likelihood of significant refrigerant cross-contamination and potential failure of both air conditioning systems and recovery/recycling equipment.
CFC-12 Automobile Motor Vehicle Air Conditioning (New Equipment/NIKs only).	HCFC Blend Beta (R- 416A).	Acceptable subject to use conditions, for passenger cars and light-duty trucks manufactured for Model Year 2016 or earlier, and for vehicles other than passenger cars or light-duty trucks.	<ul> <li>must be used with unique fittings.</li> <li>must be used with detailed labels.</li> </ul>	EPA is concerned that the existence of several substitutes in this end-use may increase the likelihood of significant refrigerant cross-contamination and potential failure of both air conditioning systems and recovery/recycling equipment.
CFC-12 Automobile Motor Vehicle Air Conditioning (New Equipment/NIKs only).	R-401C	Acceptable subject to use conditions	<ul> <li>must be used with unique fittings.</li> <li>must be used with detailed labels.</li> </ul>	EPA is concerned that the existence of several substitutes in this end-use may increase the likelihood of significant refrigerant cross-contamination and potential failure of both air conditioning systems and recovery/recycling equipment.
CFC-12 Automobile Motor Vehicle Air Conditioning (Retrofit Equipment only).	HFC-134a, R-401C, HCFC Blend Beta (R-416A).	Acceptable subject to use conditions	<ul> <li>must be used with unique fittings.</li> <li>must be used with detailed labels.</li> <li>all CFC-12 must be removed from the system prior to retrofitting.</li> <li>Refer to the text for a full description.</li> </ul>	EPA is concerned that the existence of several substitutes in this end-use may increase the likelihood of significant refrigerant cross-contamination and potential failure of both air conditioning systems and recovery/recycling equipment. No distinction is made between "retrofit" and "drop-in" refrigerants; retrofitting a car to use a new refrigerant includes all procedures that result in the air conditioning system using a new refrigerant.
*	*	* *	*	* *

#### REFRIGERANTS—ACCEPTABLE SUBJECT TO NARROWED USE LIMITS

End-use	Substitute		Decision	Comments		
*	*	*	*	*	*	*
Motor vehicle air conditioning (new equipment in passenger cars and light-duty trucks only).	HFC-134a		Acceptable for use in Model Year (MY) 2021 through MY 2025 passenger cars and light-duty trucks destined for export, where reasonable efforts have been made to ascertain that other alternatives are not technically feasible because of lack of infrastructure for servicing with alternative refrigerants in the destination country.	tion that the country to w must retain t least five year pose of demo Documentation Products in w Substitutes e tion country; Reason for re Anticipated d	infrastructure is raction that they plan to the documentation for a steer date of its postrating compliar is to include describing the substitute examined and rejection of other all late other substituters.	riptions of: e is needed; cted for the destina-

#### REFRIGERANTS—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Comments
*	* *	*	* * *
Motor vehicle air conditioning (new equipment in passenger cars and light-duty trucks only).	HFC-134a	Unacceptable as of Model Year 2021 except where allowed under narrowed use limit.	HFC-134a has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 811-97-2 and it is also known by the name 1,1,1,2-tetrafluoropropane. HFC-134a has a GWP of 1,430. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.  This listing does not prohibit the servicing or replacement of motor vehicle air conditioning systems manufactured to use HFC-134a.
Motor vehicle air conditioning (new equipment in passenger cars and light-duty trucks only).	R-406A, R-414A (HCFC Blend Xi, GHG-X4), R- 414B (HCFC Blend Omi- cron), HCFC Blend Delta (Free Zone), Freeze 12, GHG-X5, HCFC Blend Lambda (GHG-HP), R- 416A (FRIGC FR-12, HCFC Blend Beta).	Unacceptable as of Model Year 2017.	These refrigerants all contain HCFCs. They have GWPs ranging from 1,080 to 2,340 and ODPs ranging from 0.008 to 0.056. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Motor vehicle air condi- tioning (new equipment in passenger cars and light-duty trucks only).	SP34E, R–426A (RS-24, new formulation).	Unacceptable as of Model Year 2017.	These blends have GWPs ranging from approximately 1,410 to 1,510. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.

■ 3. Appendix D to subpart G of part 82 is amended by revising the third paragraph to read as follows:

Appendix D to Subpart G of Part 82— Substitutes Subject to Use Restrictions and Unacceptable Substitutes

Summary of Decisions

Refrigeration and Air Conditioning Sector Acceptable Subject to Use Conditions

\* \* \* \* \*

In addition, the use of a) R–406A/
"GHG"/"McCool", "HCFC Blend
Lambda"/"GHG-HP", R–414A/"HCFC
Blend Xi"/"GHG-X4/"Autofrost"/
"Chill-It", R–414B/"Hot Shot"/"Kar
Kool", and R–416A/"HCFC Blend
Beta"/"FREEZE 12" as CFC–12
substitutes in retrofitted MVACs, and b)
all refrigerants submitted for, and listed
in, subsequent Notices of Acceptability

as substitutes for CFC-12 in MVACs, must meet the following conditions.

\* \* \* \* \*

■ 4. Appendix U to subpart G of part 82 is added to read as follows:

Appendix U to Subpart G of Part 82— Unacceptable Substitutes and Substitutes Subject to Use Restrictions Listed in the July 20, 2015 Final Rule, Effective August 19, 2015

#### AEROSOLS—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
Propellants	HFC-125	Unacceptable as of January 1, 2016.	HFC-125 has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 354-33-6 and it is also known by the name 1,1,1,2,2-pentafluoropropane. HFC-125 has a GWP of 3,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date. Products using this propellant that are manufactured prior to January 1, 2016 may be sold, imported, exported, distributed and used after that date.
Propellants	HFC-134a	Unacceptable as of July 20, 2016, except uses listed as acceptable, subject to use conditions.	HFC-134a has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 811-97-2 and it is also known by the name 1,1,1,2-tetrafluoropropane. HFC-134a has a GWP of 1,430. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date. Products using this propellant that are manufactured prior to July 20, 2016 may be sold, imported, exported, distributed and used after that date.
Propellants	HFC-227ea and blends of HFC-134a and HFC-227ea.	Unacceptable as of July 20, 2016, except uses listed as acceptable, subject to use conditions.	HFC-227ea has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 431-89-0 and it is also known by the name 1,1,1,2,3,3,3-heptafluoropropane. HFC-134a has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 811-97-2 and it is also known by the name 1,1,1,2-tetrafluoropropane. HFC-227ea and HFC-134a have GWPs of 3,220 and 1,430, respectively. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.

#### AEROSOLS—UNACCEPTABLE SUBSTITUTES—Continued

End-use	Substitute	Decision	Further information
			Products using these propellants that are manufactured prior to July 20, 2016 may be sold, imported, exported, distributed and used after that date.
Propellants	HCFC-22 and HCFC-142b.	Unacceptable effective September 18, 2015.	Use or introduction into interstate commerce of virgin HCFC–22 and HCFC–142b for aerosols is prohibited as of January 1, 2010 under EPA's regulations at 40 CFR part 82 subpart A. These propellants have ozone depletion potentials of 0.055 and 0.065, respectively.
Solvents	HCFC-141b and blends thereof.	Unacceptable effective September 18, 2015.	Use or introduction into interstate commerce of virgin HCFC-141b for aerosols is prohibited as of January 1, 2015 under EPA's regulations at 40 CFR part 82 subpart A. HCFC-141b has an ozone depletion potential of 0.11.

#### SUBSTITUTES ACCEPTABLE SUBJECT TO USE CONDITIONS

End-use	Substitute	Decision	Use conditions	Further information
Propellants	HFC-134a	Acceptable subject to use conditions.	The classes of products listed below are acceptable for use from July 20, 2016 through December 31, 2017 and are unacceptable thereafter.  • products for functional testing of smoke detectors	HFC–134a has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 811–97–2 and it is also known by the name 1,1,1,2-tetrafluoropropane. HFC–134a has a GWP of 1,430. Use is allowed for the specified uses because of the technical and safety demands in these applications.  Aerosol products using this propellant that are manufactured prior to July 20, 2016, may be sold, imported, exported, distributed and used after that date.
Propellants	HFC-227ea and blends of HFC- 227ea and HFC-134a.	Acceptable subject to use conditions.	<ul> <li>sprays for aircraft maintenance.</li> <li>sprays containing corrosion preventive compounds used in the maintenance of aircraft, electrical equipment or electronics, or military equipment.</li> <li>pesticides for use near electrical wires or in aircraft, in total release insecticide foggers, or in certified organic use pesticides for which EPA has specifically disallowed all other lower-GWP propellants.</li> <li>mold release agents and mold cleaners.</li> <li>lubricants and cleaners for spinnerettes for synthetic fabrics.</li> <li>duster sprays specifically for removal of dust from photographic negatives, semiconductor chips, specimens under electron microscopes, and energized electrical equipment.</li> <li>adhesives and sealants in large canisters.</li> <li>document preservation sprays.</li> <li>wound care sprays.</li> <li>topical coolant sprays for pain relief.</li> <li>products for removing bandage adhesives from skin.</li> <li>Acceptable for use in metered dose inhalers approved by the U.S. Food and Drug Administration for medical purposes and unacceptable for all other uses as of July 20, 2016.</li> </ul>	HFC–227ea has a Chemical Abstracts Service Registry Number (CAS Reg. No.) of 431–89–0 and it is also known by the name 1,1,1,2,3,3,3- heptafluoropropane. HFC–227ea has a GWP of 3,220.

#### SUBSTITUTES ACCEPTABLE SUBJECT TO USE CONDITIONS—Continued

End-use	Substitute	Decision	Use conditions	Further information
				Aerosol products using this propellant that are manufactured prior to July 20, 2016 may be sold, imported, exported, distributed and used after that date.

#### REFRIGERATION AND AIR CONDITIONING—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
Retail food refrigeration (supermarket systems) (new).	HFC-227ea, R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, R-507A.	Unacceptable as of January 1, 2017.	These refrigerants have GWPs ranging from 2,729 to 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Retail food refrigeration (supermarket systems) (retrofit).	R–404A, R–407B, R–421B, R–422A, R–422C, R–422D, R–428A, R–434A, R–507A.	Unacceptable as of July 20, 2016.	These refrigerants have GWPs ranging from 2,729 to 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Retail food refrigeration (remote condensing units) (new).	HFC-227ea, R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, R-507A.	Unacceptable as of January 1, 2018.	These refrigerants have GWPs ranging from 2,729 to 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Retail food refrigeration (remote condensing units) (retrofit).	R-404A, R-407B, R-421B, R-422A, R-422C, R-422D, R-428A, R-434A, R-507A.	Unacceptable as of July 20, 2016.	These refrigerants have GWPs ranging from 2,729 to 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Retail food refrigeration (stand-alone me- dium-temperature units with a com- pressor capacity below 2,200 Btu/hr and not containing a flooded evaporator) (new).	FOR12A, FOR12B, HFC-134a, HFC-227ea, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-426A, R-428A, R-434A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, THR-03.	Unacceptable as of January 1, 2019.	These refrigerants have GWPs ranging from approximately 900 to 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date. "Medium-temperature" refers to equipment that maintains food or beverages at temperatures above 32°F (0 °C).
Retail food refrigeration (stand-alone medium-temperature units with a compressor capacity below 2,200 Btu/hr and containing a flooded evaporator) (new).	FOR12A, FOR12B, HFC–134a, HFC–227ea, KDD6, R–125/290/134a/600a (55.0/1.0/42.5/1.5), R–404A, R–407A, R–407B, R–407C, R–407F, R–410A, R–410B, R–417A, R–421A, R–421B, R–422A, R–422B, R–422C, R–422D, R–424A, R–426A, R–428A, R–434A, R–437A, R–438A, R–507A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, THR-03.	Unacceptable as of January 1, 2020.	These refrigerants have GWPs ranging from approximately 900 to 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date. "Medium-temperature" refers to equipment that maintains food or beverages at temperatures above 32°F (0 °C).
Retail food refrigeration (stand-alone me- dium-temperature units with a com- pressor capacity equal to or greater than 2,200 Btu/hr) (new).	FOR12A, FOR12B, HFC-134a, HFC-227ea, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-426A, R-434A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), RS-44 (2003 formulation), SP34E, THR-03.	Unacceptable as of January 1, 2020.	These refrigerants have GWPs ranging from approximately 900 to 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date. "Medium-temperature" refers to equipment that maintains food or beverages at temperatures above 32°F (0 °C).
Retail food refrigeration (stand-alone low- temperature units) (new).	HFC-227ea, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407A, R-407B, R-407C, R-407F, R-410A, R-410B, R-417A, R-421A, R-421B, R-422A, R-422B, R-422C, R-422D, R-424A, R-428A, R-434A, R-437A, R-438A, R-507A, RS-44 (2003 formulation).	Unacceptable as of January 1, 2020.	These refrigerants have GWPs ranging from approximately 1,800 to 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date. "Low-temperature" refers to equipment that maintains food or beverages at temperatures at or below 32°F (0 °C).

#### REFRIGERATION AND AIR CONDITIONING—UNACCEPTABLE SUBSTITUTES—Continued

End-use	Substitute	Decision	Further information
Retail food refrigeration (stand-alone units only) (retrofit).	R-404A, R-507A	Unacceptable as of July 20, 2016.	These refrigerants have GWPs of approximately 3,922 and 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Vending machines (new only).	FOR12A, FOR12B, HFC-134a, KDD6, R-125/290/134a/600a (55.0/1.0/42.5/1.5), R-404A, R-407C, R-410A, R-410B, R-417A, R-421A, R-422B, R-422C, R-422D, R-426A, R-437A, R-438A, R-507A, RS-24 (2002 formulation), SP34E.	Unacceptable as of January 1, 2019.	These refrigerants have GWPs ranging from approximately 1,100 to 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Vending machines (retrofit only).	R-404A, R-507A	Unacceptable as of July 20, 2016.	These refrigerants have GWPs of approximately 3,922 and 3,985. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.

· Anticipated date other substitutes will be available and projected time for switch-

ing.

Fo	FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS					
End-use	Substitute	Decision	Narrowed use limits	Further information		
Rigid Polyurethane: Appliance.	HFC-134a, HFC- 245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2020, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.		
Rigid Polyurethane: Commercial Refrigera- tion and Sandwich Panels.	HFC-134a, HFC- 245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2020, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.		
Flexible Polyurethane	HFC-134a, HFC- 245fa, HFC-365mfc, and blends thereof.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2017, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed;  • Substitutes examined and rejected;  • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  • Anticipated date other substitutes will be available and projected time for switching.		
Rigid Polyurethane: Slabstock and Other.	HFC-134a, HFC- 245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2019, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or		

#### FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS—Continued

End-use	Substitute	Decision	Narrowed use limits	Further information
Rigid Polyurethane and Polyisocyanurate Laminated Boardstock.	HFC-134a, HFC- 245fa, HFC-365mfc and blends thereof.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2017, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Rigid Polyurethane: Marine Flotation Foam.	HFC-134a, HFC- 245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2020, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed;  • Substitutes examined and rejected;  • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  • Anticipated date other substitutes will be available and projected time for switching.
Polystyrene: Extruded Sheet.	HFC-134a, HFC- 245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2017, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Polystyrene: Extruded Boardstock and Billet.	HFC-134a, HFC- 245fa, HFC-365mfc, and blends thereof; Formacel TI, Formacel B, and Formacel Z-6.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2021, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Integral Skin Polyurethane.	HFC-134a, HFC- 245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2017, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.

#### FOAM BLOWING AGENTS—SUBSTITUTES ACCEPTABLE SUBJECT TO NARROWED USE LIMITS—Continued

End-use	Substitute	Decision	Narrowed use limits	Further information
Polyolefin	HFC-134a, HFC- 245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2020, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed; • Substitutes examined and rejected; • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or • Anticipated date other substitutes will be available and projected time for switching.
Phenolic Insulation Board and Bunstock.	HFC-143a, HFC-134a, HFC-245fa, HFC- 365mfc, and blends thereof.	Acceptable Subject to Narrowed Use Limits.	Acceptable from January 1, 2017, until January 1, 2022, only in military or space- and aeronautics-related applications where reasonable efforts have been made to ascertain that other alternatives are not technically feasible due to performance or safety requirements.	Users are required to document and retain the results of their technical investigation of alternatives for the purpose of demonstrating compliance. Information should include descriptions of:  • Process or product in which the substitute is needed;  • Substitutes examined and rejected;  • Reason for rejection of other alternatives, e.g., performance, technical or safety standards; and/or  • Anticipated date other substitutes will be available and projected time for switching.

#### UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
All Foam Blowing End-uses	HCFC-141b and blends thereof.	Unacceptable effective September 18, 2015.	HCFC-141b has an ozone depletion potential of 0.11 under the Montreal Protocol. EPA previously found HCFC-141b unacceptable in all foam blowing enduses (appendix M to subpart G of 40 CFR part 82). HCFC-141b has an ozone depletion potential (ODP) of 0.11.
All Foam Blowing end-uses	HCFC-22, HCFC-142b, and blends thereof.	Unacceptable effective September 18, 2015.	Use or introduction into interstate commerce of virgin HCFC-22 and HCFC-142b for foam blowing is prohibited after January 1, 2010 under EPA's regulations at 40 CFR part 82 subpart A unless used, recovered, and recycled. These compounds have ODPs of 0.055 and 0.065, respectively.
Flexible Polyurethane	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	These foam blowing agents have global warming potentials (GWPs) ranging from 725 to 1,430. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Polystyrene: Extruded Sheet	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Phenolic Insulation Board and Bunstock.	HFC-143a, HFC-134a, HFC-245fa, HFC- 365mfc, and blends thereof.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	These foam blowing agents have GWPs ranging from 725 to 4,470. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Integral Skin Polyurethane	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Rigid Polyurethane: Slabstock and Other.	HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.	Unacceptable as of January 1, 2019 except where allowed under a narrowed use limit.	These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Rigid Polyurethane and Polyisocyanurate Lami- nated Boardstock.	HFC-134a, HFC-245fa, HFC-365mfc and blends thereof.	Unacceptable as of January 1, 2017 except where allowed under a narrowed use limit.	These foam blowing agents have GWPs ranging from 725 to 1,430. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.

#### UNACCEPTABLE SUBSTITUTES—Continued

End-use	Substitute	Decision	Further information
Rigid Polyurethane: Marine Flotation Foam.	HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6;.	Unacceptable as of Janu- ary 1, 2020 except where allowed under a narrowed use limit.	These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Rigid Polyurethane: Com- mercial Refrigeration and Sandwich Panels.	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Unacceptable as of Janu- ary 1, 2020 except where allowed under a narrowed use limit.	These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Rigid Polyurethane: Appliance.	HFC-134a, HFC-245fa, HFC-365mfc and blends thereof; Formacel TI, and Formacel Z-6.	Unacceptable as of Janu- ary 1, 2020 except where allowed under a narrowed use limit.	These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Polystyrene: Extruded Boardstock and Billet.	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, Formacel B, and Formacel Z-6.	Unacceptable as of Janu- ary 1, 2021 except where allowed under a narrowed use limit.	These foam blowing agents have GWPs ranging from higher than 140 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.
Polyolefin	HFC-134a, HFC-245fa, HFC-365mfc, and blends thereof; Formacel TI, and Formacel Z-6.	Unacceptable as of Janu- ary 1, 2020 except where allowed under a narrowed use limit.	These foam blowing agents have GWPs ranging from higher than 370 to approximately 1,500. Other substitutes will be available for this end-use with lower overall risk to human health and the environment by the status change date.

#### FIRE SUPPRESSION AND EXPLOSION PROTECTION AGENTS—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
Total Flooding	HCFC-22	Unacceptable effective September 18, 2015.	Use or introduction into interstate commerce of virgin HCFC-22 for total flooding fire suppression and explosion protection is prohibited as of January 1, 2010 under EPA's regulations at 40 CFR part 82 subpart A. This chemical has an ozone depletion potential of 0.055.

#### STERILANTS—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
Sterilants	Blends containing HCFC–22.	Unacceptable effective September 18, 2015.	Use or introduction into interstate commerce of virgin HCFC-22 for sterilants is prohibited as of January 1, 2010 under EPA's regulations at 40 CFR part 82 subpart A. This chemical has an ozone depletion potential of 0.055.

#### ADHESIVES, COATINGS AND INKS—UNACCEPTABLE SUBSTITUTES

End-use	Substitute	Decision	Further information
Adhesives, coatings and inks.	HCFC-141b and blends thereof.	Unacceptable effective September 18, 2015.	Use or introduction into interstate commerce of virgin HCFC-141b for adhesives, coatings and inks is prohibited as of January 1, 2015 under EPA's regulations at 40 CFR part 82 subpart A. This chemical has an ozone depletion potential of 0.11.

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#### Part III

### Department of Justice

Drug Enforcement Administration

Syed Jawed Akhtar-Zaidi, M.D.; Decision and Order; Notice

#### **DEPARTMENT OF JUSTICE**

# Drug Enforcement Administration [Docket No. 14–2]

### Syed Jawed Akhtar-Zaidi, M.D.; Decision and Order

On February 10, 2014, Administrative Law Judge (ALJ) Christopher B. McNeil issued the attached Recommended Decision. Both parties filed Exceptions to the ALJ's Recommended Decision.

Having reviewed the entire record, including the parties' Exceptions, I have decided to adopt the ALJ's findings of fact except as discussed below. I further adopt the ALJ's conclusions of law that:

(1) Respondent issued prescriptions for controlled substances to three undercover officers outside the usual course of professional practice and which lacked a legitimate medical purpose:

(2) Respondent violated Federal law when he issued controlled substance prescriptions which did not include the

patient's address;

- (3) Respondent violated Ohio law requiring that he "complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of [his] patients," when, with respect to the three undercover officers, he "falsely reported the extent and nature of his examination of [them] and falsely reported the patients' reports of pain";
- (4) Respondent "failed to comply with the requirements of Ohio law applicable to the treatment of chronic pain." R.D. 81–86. Finally, I adopt the ALJ's ultimate conclusions of law that the Government has met its *prima facie* burden of showing that "Respondent's continued . . . registration is inconsistent with the public interest" and that "Respondent has failed to rebut the Government's *prima facie* case." *Id.* at 87.

According to the ALJ's Recommended Decision, Respondent's registration was due to expire on June 30, 2014, and according to the registration records of the Agency, of which I take official notice, see 5 U.S.C. 556(e), Respondent has not filed either a renewal or new application. While ordinarily, these findings would render a case moot, see Ronald J. Riegel, 63 FR 67132, 67133 (1998), this Agency has recognized that where a registrant is served with an Immediate Suspension Order, there may be collateral consequences which preclude a finding of mootness. Here for example, the Immediate Suspension

Order authorized the Government to seize any controlled substances it found at Respondent's registered location, see ALJ Ex. 1, at 4 (citation omitted); and pursuant to 21 U.S.C. 824(f), "[u]pon a revocation order becoming final, all such controlled substances . . . shall be forfeited to the United States" and "[a]ll right, title, and interest in such controlled substances . . . shall vest in the United States upon a revocation order becoming final." See also 21 CFR 1301.36(f)). Moreover, the Agency has held that a registrant, who has been issued an Immediate Suspension Order, cannot defeat the effect of this provision by allowing his registration to expire. Meetinghouse Community Pharmacy. Inc., 74 FR 10073, 10074 n.5 (2009).

Accordingly, on May 8, 2015, the former Administrator issued an Order directing the parties to address whether the case was moot. Thereafter, both parties filed responses asserting that the case remains a live controversy, with the Government specifically noting that various controlled substances including Demerol, morphine sulfate, hydrocodone, and midazolam were seized from Respondent's office during service of the Immediate Suspension Order. Gov't Response to Order, at 2. The Government further represents that there are no other proceedings pending to determine title to the drugs and therefore requests that I issue a final order to resolve this issue.

Accordingly, I conclude that this proceeding presents the collateral consequence of who has title to the controlled substances seized by the Government. While I do not adopt the ALJ's recommended order that I revoke Respondent's registration and deny any pending application to renew or modify his registration, I will affirm the issuance of the Immediate Suspension Order and declare that all right, title, and interest in the seized drugs is forfeited to the United States. A discussion of Respondent's Exceptions follows.<sup>2</sup>

#### Exception One—The ALJ Arbitrarily and Capriciously Barred Respondent From Presenting the Testimony of His Expert Witness, His Employees, and His Patients

Respondent argues that the ALJ's refusal to allow him to present testimony from his expert, Dr. Richard Stieg, three of his employees, and his patients, "was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law." Resp. Exceptions, at 1–2. While I find the ALJ's ruling denying Respondent the right to call Dr. Stieg to be problematic, for reasons explained below, I hold that Respondent has not demonstrated that the ALJ committed prejudicial error. I further find that Respondent has failed to demonstrate that the ALJ erred when he barred the employees and the patients from testifying, let alone that the error was prejudicial.

# The ALJ's Ruling Barring Dr. Stieg's Testimony

Respondent argues that even before the proceeding was initiated, "the Government had several months in which to . . . obtain an expert witness" and have the expert review the evidence against him. Resp. Exceptions, at 2. By contrast, Respondent argues he "had a very limited period of time in which to . . . retain an expert and have the expert review the documents and files" and form his opinion. *Id.* Noting that the ALJ "placed near complete reliance on the testimony of the Government's expert," *id.* at 3, Respondent contends

no court has ever questioned the Agency's interpretation that it is required to consider (although not necessarily make findings with respect to) each of the public interest factors in a revocation proceeding. See Dewey C. MacKay, 664 F.3d 808, 816 (10th Cir. 2011) (noting, in revocation proceeding, that "[t]he agency is required to consider five factors '[i]n determining the public interest'"); id. at 819 (upholding agency's determination that evidence that physician diverted controlled substances was relevant under both factors two and four); Morall v DEA, 412 F.3d 165, 173 (D.C. Cir. 2005) (noting, in revocation proceeding, that "[s]ection 823(f) provides the factors to be considered '[i]n determining the public interest" and listing all five factors).

Thus, the issue has been conclusively decided. Because the ALI's decision is only a recommendation, the Agency has no obligation to publish any portion of it, let alone that which persists in re-arguing that which has been long decided. See Iran Air v. Kugelman, 996 F.2d 1253, 1260 (D.C. Cir. 1993) (quoting Joseph Zwerdling, Reflections on the Role of an Administrative Law Judge, 25 Admin. L. Rev. 9, 12-13 (1973) (an ALJ "'is governed, as is the case of any trial court, by the applicable and controlling precedents. These precedents include . . . the agency's policies as laid down in its published decisions. . . . Once the agency has ruled on a given matter . . . it is not open to reargument by the administrative law judge' '')). Accordingly, I decline to publish the ALJ's discussion regarding the applicability of factor two in revocation proceedings.

<sup>&</sup>lt;sup>1</sup> All citations to the Recommended Decision are to the slip opinion as issued by the ALJ.

<sup>&</sup>lt;sup>2</sup> The Government takes exception to the ALJ's discussion of factor two and whether the Agency has properly applied it in revocation proceedings because the factor refers only to "the applicant's" experience in dispensing controlled substances. *See* R.D. at 54–58. The Government's exception is well taken.

Pursuant to Congress's direction in 21 U.S.C. 824(a)(4) that the Agency may revoke a registration "upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section," every Administrator and Deputy Administrator who has exercised the authority granted by section 824 has rejected the ALJ's view. Moreover, in Clair L. Pettinger, M.D., 78 FR 61592 (2013), the Administrator thoroughly addressed and rejected the ALJ's reasoning. Indeed,

that "expert testimony [was] critical to establishing [his] defense," *id.* at 2, and that Dr. Stieg (his expert), "was prepared to testify that contrary to the Government's position, he did not fail to meet the standard of care in pain medicine." *Id.* at 3.

Respondent further contends that he "was placed in a perilous position by the" ALJ, apparently because after Respondent identified Dr. Stieg and disclosed "his expected testimony," he "also discovered that Dr. Stieg" had a serious medical condition and was to undergo treatment on the dates set for the hearing (December 16–17, 2013) and "would be unable to testify." *Id.* Respondent then notes that "[u]pon discovering this information," he immediately moved for a continuance of the proceeding, but that the ALJ denied his motion.

Respondent further argues that the ALJ's basis for denying his motion was inconsistent with agency precedent. In his Recommended Decision, the ALJ explained that he found Dr. Stieg's testimony "would likely have little probative value, as the witness did not appear to be familiar with Ohio medical practice standards." R.D. at 4. Respondent argues that the ALJ's reason is "arbitrary, capricious, an abuse of discretion, and not in accord with DEA precedent," noting that in Mireille *Lalanne,* 78 FR 47750, 47759 (2013), the Agency held that evidence as to "generally recognized and accepted medical practices" may be admitted to show "the usual course of professional practice" under the CSA and the Agency's regulations, R.D. at 4 (other citation omitted). He then notes that several of the factors which the Agency is required to consider under the public interest standard are "not set by state law." Resp. Exceptions, at 5. Moreover, Respondent suggests that the ALJ made inconsistent findings when he held that Respondent had not demonstrated that the exclusion of Dr. Stieg's testimony would cause him "substantial prejudice," while at the same time he held that the Government would be prejudiced by the testimony. Id. at 4.

Finally, Respondent notes that while the ALJ had initially considered allowing Dr. Stieg to testify through video teleconference (and be taken out of order), he reversed his position after Respondent invoked his Fifth Amendment privilege and refused to testify when called as a witness by the Government. *Id.* at 5 (citing Tr. 248). According to Respondent, the ALJ's ruling was an "attempt to punish Respondent for exercising his constitutional right." *Id.* 

While some of Respondent's arguments are well taken, I hold that Respondent has failed to demonstrate prejudicial error. See 5 U.S.C. 706. As several federal courts have explained, an ALJ's discretion "includes the power to make reasonable, nonarbitrary decisions regarding the admission or exclusion of evidence." Gunderson v. Department of Labor, 601 F.3d 1013, 1021 (10th Cir. 2010). However, even where it is shown that an ALJ erred in excluding evidence, that error must "'prejudicially affect a substantial right of a party.'" Id. (quoting Sanjuan v. IBP, Inc., 160 F.3d 1291, 1296 (10th Cir. 1998)). See also Air Canada v. Department of Trans., 148 F.3d 1142, 1156 (D.C. Cir. 1998) ("As incorporated into the APA, the harmless error rule requires the party asserting error to demonstrate prejudice from the error.") (citing 5 U.S.C. 706).

Moreover, "[a]n error is prejudicial only 'if it can be reasonably concluded that with . . . such evidence, there would have been a contrary result.'" *Gunderson*, 601 F.3d at 1021 (quoting *Sanjuan*, 160 F.3d at 1296). Applying this standard, Respondent cannot prevail.

According to Respondent's proffer, "Dr. Stieg would have testified that there is no 'gold standard' or one defined standard which defines with certainty the accepted and prevailing standards of care for pain medicine medical services" and that "whether a physician has met the accepted and prevailing standards of care for pain medicine service is a case by case analysis, taking into account the individual circumstances of each patient and the relevant medical decisions in connection with the treatment of that patient." Resp. Offer of Proof, at 3.

Moreover, Dr. Stieg "would have testified that a physician in [Respondent's] position has an ethical duty to believe what his patient tells him regarding his or her medical condition, and has a duty to attempt to provide appropriate treatment which he believes helps his patient with the condition the patient represents to him," and that it is "reasonable and ethically imperative to believe" the patient until a "physician is presented with objective evidence that the patient is lying . . . or is otherwise noncompliant." Id. at 3-4. Dr. Stieg would have further testified that various actions Respondent took in prescribing to the undercover officers were "appropriate and . . . within the accepted and prevailing standard of care," as well as being "appropriate to

protect against addiction, diversion, and misuse." *Id.* at 4.

Respondent further proffered that Dr. Stieg would testify "that the physician/patient relationship for pain medicine must evolve over time," *id.*, and that the "approximately three to four month[]" periods in which Respondent treated the undercover officers "is an extremely short period which provided additional difficulties [in] discover[ing] the lies told to him by the undercover agents." *Id.* at 4–5.

On the issue of the adequacy of the physical exams, Respondent proffered that "Dr. Stieg would testify that there is no single standard to determine exactly what an adequate physical examination requires in every circumstance" and that "there is a consensus standard that a physical examination should focus on the cause of the pain." *Id.* at 5. Moreover, Dr. Stieg would have testified "that a full physical examination is usually not required for every pain medicine encounter." *Id.* 

Respondent also proffered that "Dr. Stieg would have testified that the diagnosis made by Dr. Zaidi for each undercover agent were [sic] within the accepted and prevailing standards of care," that the initial "diagnosis often becomes clearer as the physician/patient relationship yields more information over time," and while an "MRI and further testing may have revealed [a] more specific pathological diagnosis

. . . the diagnosis of lumbago and lumbar radiculosis can be justified, pending further analysis." Id. at 6. Finally, Respondent proffered that Dr. Stieg would have testified that given "the short treatment period, the standard of care" did not require that Respondent demand that the undercover officers undergo "additional expensive treatment at that time, such as physical therapy," and that Respondent acted within the standard of care by considering the undercover officers' representations that they were unable "to pay for the" MRIs and alternative treatments. Id. Thus, Dr. Stieg would have testified that Respondent's "treatment of the undercover agents was for legitimate medical purposes." Id. at 3.

I agree with Respondent that it was not reasonable to require him to identify his expert witness, have the expert review the Government's evidence against him, and prepare an adequate summary of the expert's testimony within the time period provided for in the ALJ's pre-hearing ruling. Indeed, it is not clear on this record how Respondent could have provided an adequate summary of his expert's

testimony in his prehearing statement when, under the ALJ's Order for Prehearing Statements, he was required to file the statement one week before the parties were even required to exchange their proposed exhibits. See ALI Exs. 3 & 4. I also agree with Respondent that it was not reasonable for the ALJ to deny his request for a continuance after he determined that his expert was unable to attend the hearing because he needed to undergo treatment for a serious medical condition. Finally, I agree with Respondent that under agency precedent, evidence as to "generally recognized and accepted medical practices" remains admissible to show whether a physician acted within "the usual course of professional practice" under federal law. See Mireille Lalanne, 78 FR 47750, 47759 (2013). While Dr. Stieg's apparent lack of familiarity with the State of Ohio's medical practice standards might properly lead to giving his testimony less weight, especially when it was weighed against that of an expert who is knowledgeable in the Ohio standards and who has served as an expert reviewer for the State's medical board, it was not a per se bar to its admission.

This aside, much of the proffered testimony is consistent with that given by the Government's expert. But most significantly, this is not a case in which the evidence is limited to the testimony of dueling experts. Rather, the Government presented substantial evidence beyond the testimony of its expert to support the conclusion that Respondent acted outside the usual course of professional practice and lacked a legitimate medical purpose in issuing the prescriptions to the undercover officers. Thus, even if Dr. Stieg had testified that Respondent acted within the accepted standard of care in making the diagnoses and prescribing controlled substances to the undercover patients, as ultimate factfinder, I would not find this sufficient to reject the ALJ's findings. Gunderson, 601 F.3d at 1021 (quoting Sanjuan, 160 F.3d at 1296).

Here, with respect to each of the undercover officers, the record is replete with evidence that Respondent falsified each officer's medical record at every visit to document both: (1) The performance of physical exam tests which he never conducted, and (2) pain levels which were higher than the officers actually reported. Nothing in the proffered testimony of Dr. Stieg refutes the fair inference which arises from the falsifications—that Respondent falsified the records in order to justify the prescribing of controlled substances, and that in prescribing the controlled

substances, Respondent acted outside the usual course of professional practice and lacked a legitimate medical purpose. See 21 CFR 1306.04(a) ("A prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual

medical purpose by an individual practitioner acting in the usual course of

professional practice.").

This conclusion is buttressed by Respondent's invocation of his Fifth Amendment privilege when called to testify by the Government. As the Supreme Court has explained, "the Fifth Amendment does not forbid adverse inference against parties to civil actions when they refuse to testify in response to probative evidence offered against them." Baxter v. Palmigiano, 425 U.S. 308, 318 (1976) (emphasis added); see also MacKav v. DEA, 664 F.3d 808, 820 (10th Cir. 2011) (quoting *Keating* v. Office of Thrift Supervision, 45 F.3d 322, 326 (9th Cir. 1995) ("Not only is it permissible to conduct a civil [administrative] proceeding at the same time as a related criminal proceeding, even if that necessitates invocation of the Fifth Amendment privilege, but it is even permissible for the trier of fact to draw adverse inferences from the invocation of the Fifth Amendment in a civil [administrative] proceeding.")); Hoxie v. DEA, 419 F.3d 477, 483 (6th Cir. 2005).

In its prehearing statement, the Government provided notice that it intended to call Respondent to testify "that his treatment of the undercover officers fell below accepted medical standards and that the controlled drugs [were not] prescribed in the usual course of professional practice or for a legitimate medical purposes," as well as "that his documentation of his examinations of [each undercover officer] was inaccurate and not based on objective data that he gathered during the exams." ALJ Ex. 8. Respondent's invocation of his Fifth Amendment privilege, considered in light of the probative evidence weighed by the ALJ, thus supports the inference that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to the undercover officers.<sup>3</sup> See T.J. McNichol,

77 FR 57133, 57150 (2012) (drawing adverse inference that physician knowingly diverted controlled substances when he failed to testify "notwithstanding the substantial probative evidence of irregularities in his prescribing practices").<sup>4</sup>

# The ALJ's Ruling Barring Testimony From Respondent's Employees

Respondent further argues that the ALJ acted arbitrarily and capriciously when he barred the testimony of three employees (C.B., J.B., and R.Z.). Exceptions, at 5–6. Respondent maintains that the employees "were directly involved in the patient care of the undercover [officers] and were also interviewed by the . . . Agents when they raided [his] office." *Id.* at 5.

In his proffer, Respondent stated that C.B. is a certified medical assistant who took each undercover officer's history and that she "did extensive histories on

<sup>4</sup>I further find that Respondent has not demonstrated that the ALJ committed prejudicial error when he barred Dr. Stieg's testimony. As noted above, Respondent also contended that the ALJ's ruling barring Dr. Stieg's testimony was an attempt to punish him for exercising his Fifth Amendment privilege. For purposes of resolving his contention, I assume, without deciding, that the ALJ violated Respondent's rights under the Fifth Amendment when he relied on Respondent's failure to testify as a ground for his ruling. See Tr. 248.

However, even in criminal cases, the Supreme Court has held that a violation of a defendant's Fifth Amendment privilege is subject to harmless-error analysis. Neder v. United States, 527 U.S. 1, 18 (1999) ("The erroneous admission of evidence in violation of the Fifth Amendment's guarantee against self-incrimination . . . and the erroneous exclusion of evidence in violation of the right to confront witnesses guaranteed by the Sixth Amendment . . . are both subject to harmless-error analysis under our cases."). In this proceeding, the standard for assessing whether an error is prejudicial is whether "it can be reasonably concluded that with . . . such evidence, there would have been a contrary result." Gunderson, 601 F.3d at 1021 (quoting Šanjuan, 160 F.3d at 1296). As explained above, Respondent has not made such a showing. See United States v. Local 560, Int'l Bhd. of Teamsters, 780 F.2d 267, 292 n.32 (3d Cir. 1985) (holding that "while the district court erred in drawing an [adverse inference from a litigant's invocation of the Fifth Amendment], that error was harmless in light of the independent evidence supporting the district court's conclusion") (citation omitted).

In justifying his refusal to grant a continuance to Respondent, the ALJ also explained that he was "guided by the expectation that where doing so is not inconsistent with a litigant's rights under the Due Process Clause or the Administrative Procedure Act, I should endeavor to submit the certified record of these proceedings to the Administrator . not later than the 150th day after the issuance of an immediate suspension (excepting any days caused by Respondent's own actions)." R.D. at 4-5. However, even where an immediate suspension order has been issued, the Administrator has clearly instructed the Agency's ALJs that they may grant a continuance upon a registrant's request. Here, but for the fact that Respondent cannot show prejudicial error, I would have remanded this matter.

<sup>&</sup>lt;sup>3</sup> The ALJ also found credible the testimony of a DEA Diversion Investigator that during an interview, Respondent was asked why the pain levels documented in the medical record of one the undercover officers were different than what the undercover officer had said during the visits. R.D. 27 (citing Tr. 620). While Respondent was allowed to look at the undercover chart, Tr. 621, he "did not have a response" to the question. *Id.* at 620. This testimony, which was unrefuted, also supports an inference that Respondent falsified the undercover officers' medical records.

them" as well as other patients. Resp. Offer of Proof, at 9-10. C.B. would also have testified to the procedures used by Respondent in obtaining urine drug screens and reports from the Ohio prescription monitoring program (OARRS). Id. at 10. Moreover, C.B. would have testified regarding Respondent's procedures for using "random urine drug screening and access to the OARRS database with regard to the patients whose charts were offered as Respondent's exhibits, as well as her explanation to patients regarding the [pain] contract." Id. C.B. would have also testified as to various patients Respondent discharged because they "engaged in the use of illegal drugs and/or the misuse of controlled substances prescribed by" Respondent, and finally, C.B. would have testified to Respondent's treatment of various patients and "how [he] has helped these patients regain functionality and control over their debilitating pain." *Id.* 

According to his proffer, R.O. would have largely duplicated C.B.'s testimony regarding Respondent's treatment of the patients, whom he helped to regain functionality and control of their pain, as well as those patients who were discharged for using either illegal drugs or for misusing drugs he had prescribed. *Id.* at 11. R.O. would also have "testified regarding the contract signed by the undercover agents and her explanation to those agents of the contents of the contract." *Id.* 

Finally, J.B. "would have testified regarding her observations concerning [Respondent's] interaction with and treatment of patients including the undercover agents and those patients" identified in Respondent's Exhibits A through R, as well as regarding the patients that Respondent discharged. *Id.* at 12. J.B. would also have testified that she is the record custodian for Respondent's practice and that these records were authentic. *Id.* 

The ALJ barred Respondent from presenting the testimony of these three witnesses because the substance of their testimony was not timely disclosed and did not sufficiently establish relevance. Here, in contrast to the ALJ's rulings on Respondent's proposed expert, I conclude that the ALJ did not err in barring the testimony on the ground that it was not timely disclosed. Respondent had more than one month from the date of the ALJ's prehearing order to determine whether his employees could offer relevant evidence in the matter and a week from the time the Government provided a detailed summary of the testimony of each of its witnesses to disclose their anticipated testimony. Moreover, Respondent's proffer (which

was filed even after the testimonial phase of the hearing was concluded) does not identify any material fact which any of the employees would have refuted. Accordingly, I conclude that Respondent has also failed to establish prejudice.<sup>5</sup>

#### The ALJ's Rulings Barring Evidence Regarding Respondent's Treatment of Other Patients

Respondent also sought to elicit testimony from ten patients regarding the care they received from Respondent and how his treatment of them 'dramatically improved their lives, functionality, and ability to tolerate their ongoing pain." Resp. Proffer, at 13; see also Resp. Exceptions, at 1 & 6.6 Because DEA is not a state medical board, whether Respondent improved the lives and functionality of these patients is not relevant under any of the public interest factors. While evidence of Respondent's lawful prescribing and compliance with federal and state controlled substances rules with respect to these patients would be relevant under the public interest standard, no such proffer was made. Accordingly, the ALJ did not err in barring this testimony.7

<sup>5</sup> While the proffered testimony was arguably relevant to an assessment of Respondent's experience in dispensing controlled substances (factor two) and his compliance with applicable laws related to controlled substances (factor four), the fact that a physician engaged in the legitimate practice of medicine with respect to other patients does not refute a *prima facie* showing that a physician knowingly diverted controlled substances. See MacKay v. DEA, 664 F.3d at 808, 819 (10th Cir. 2011) ("Although Dr. MacKay may have engaged in the legitimate practice of pain medicine for many of his patients, the conduct found by the Deputy Administrator with respect to [the two patients] is sufficient to support her determination that his continued registration is inconsistent with the public interest."); see also Jayam Krishna-Iyer, 74 FR 459, 463 (2009) (holding that, even assuming that physician has treated thousands of other patients in compliance with the CSA, these prescribings did not "render her prescribings to the undercover officers any less unlawful . . . [b]ecause under law, registration is limited to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals[;] [ thus] every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of her professional career").

<sup>6</sup>Respondent also proffered that Dr. Stieg would have testified regarding the patients whose records were offered in Respondent's Exhibits A through R, as well as those patients Respondent discharged for noncompliance, and that Respondent met the standard of care in treating both categories of patients. Resp. Offer of Proof, at 7–9. While the ALJ also barred this testimony, Respondent does not raise the issue in his Exceptions. Therefore, I deem it waived.

<sup>7</sup>Respondent's proffered exhibits also includes his curriculum vitae showing his professional experience, as well as certificates showing that he Exception Two—The ALJ Erred in Applying Ohio Revised Code § 4731.052 and Ohio Admin. Code § 4731–21–02 as the Standard for Determining Whether Respondent Violated 21 CFR 1306.04(a)

Respondent argues that "the Government's expert failed to establish with any degree of medical certainty the standard of care which Respondent... failed to meet" and that the ALJ erred in applying Ohio Revised Code § 4731.052 and Ohio Admin. Code § 4731-21-02 "as the sole standard" when he held that Respondent violated 21 CFR 1306.04(a) when he prescribed to the undercover officers. Resp. Exceptions, at 6. Respondent argues that the ALI's reliance on these provisions was misplaced because they apply only to the treatment of chronic or intractable pain and not acute pain, which was the condition presented by the undercover officers. Id. at 7.

I reject Respondent's exception. Contrary to his contention, the ALJ specifically acknowledged (as did the Government's expert) that the Ohio provisions did "not apply during that phase of treatment where the diagnosis is of acute pain, but appl[ied] only after the treatment extend[ed] past twelve weeks." R.D. at 69. However, as the ALJ explained, Ohio law defines "chronic pain" as "pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months." Id. at 70. Here, each of three undercover officers received controlled substances from Respondent for more than three months after they initially saw Respondent and received a controlledsubstance prescription.8 Yet, as the

is a diplomate of the American Board of Physical Medicine and Rehabilitation, with a subspecialty of pain medicine; a diplomate of the American Board of Pain Medicine; a Diplomate of the American Board of Electrodiagnostic Medicine; and a Fellow of Interventional Pain Practice. To be sure, this evidence may have had some probative value in assessing his experience as a dispenser of controlled substances. However, in his Exceptions, Respondent makes no argument that the ALJ improperly excluded these exhibits.

<sup>8</sup>I agree with Respondent that the undercover agents did not present as suffering from "intractable pain," as that term is defined by Ohio's regulation. Resp. Exceptions, at 7. The regulation defines "intractable pain" as "a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found." Ohio Admin. Code § 4731–21–01(G). Here, Respondent did not make a diagnosis of intractable pain with respect to any of the undercover officers. Nor is it clear how any such diagnosis could have been made given that Respondent did not perform anything more than a cursory physical exam at the

Continued

Government's expert testified, Respondent did not comply with the heightened standards imposed on prescribing controlled substances to treat chronic pain.

Moreover, notwithstanding that neither of the Ohio provisions applied in the initial three-month period of the undercover officers' treatment, the record contains substantial evidence to support the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed to each of the undercover officers during this period. For example, with respect to Patient Tyler Williams, Respondent diagnosed him as having "thoracic and lumbar radiculitis, lumbago." GX 12, at 8. However, the Government's expert testified that he had reviewed the video recording of the UC's first visit and found that while Respondent documented that he had performed numerous tests during the physical examination, many of the tests were actually not performed. Tr. 71-76. The expert thus explained that his "impression of the physical examination is that it is falsified, it is embellished, and it is inaccurate, to the point that much of it, though documented here, was not performed."

The Government's expert then explained that Respondent's diagnosis was not justified by the patient's history and the physical examination and that the diagnosis of radiculitis was "blatantly inaccurate." *Id.* at 78. The expert further opined that Respondent's issuance of a prescription for Percocet was "not justified by the presentation of the patient." *Id.* at 79.

The progress note for the UC's second visit states that he had "moderate tenderness and spasm in paralumbar muscles with guarding in forward flexion" and that the "lower extremity examination is normal to sensory and motor testing." GX 12, at 12. Here again, the Government's expert reviewed the

initial visit and generally no exam at subsequent visits, and never recommended that his patients even modify their daily activities, let alone undergo physical therapy. Tr. 118, 125. I therefore reject the ALJ's conclusion of law Number 11. R.D. at 84–85 (concluding "that Respondent failed to comply with the requirements of Ohio law for the treatment of intractable pain").

However, based on the length of the prescribings, I agree with the ALJ's conclusion that Respondent failed to comply with Ohio's chronic pain statute. See Ohio Rev. Code § 4731.052. This provision defines "chronic pain" as "pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months." Id. at § (A)(1). Thus, this provision does not appear to require that the pain be incapable of being cured.

recording and transcript of the visit and found that Respondent did not perform a physical examination (while documenting that he did) and that the findings were falsified. Tr. 80-81. He further noted that while the progress note stated that the treatment plan included a home exercise program (in addition to controlled substances), there was no evidence of "any educational endeavor that would allow someone to conduct a home exercise program." Id. at 81; see also id. at 83-85. As for Respondent's prescription for Percocet, the expert opined that it was "not justified" and was "prescribed outside the usual course of professional practice." Id. at 86.

With respect to the third visit, the Government's expert similarly observed that there was no evidence that Respondent had examined the UC's lumbar spine or performed sensory or motor testing of his lower extremities, id. at 88, although Respondent documented having done so. GX 12, at 11. The expert also noted that the progress note documented a pain level of "5," which was higher than what the UC reported, Tr. 88, Indeed, the UC reported that his present pain level was a "2," and that the worst it had been in the past week was a "3." GX 12, at 18. Once again, the expert testified that Respondent's diagnosis of lumbar radiculitis could not be justified based on the "the entirety of the history and the physical examination." Tr. 89.

With respect to the UC's fourth and fifth visits, the expert again found that there was no justification for the lumbar radiculitis diagnosis and that Respondent did not physically examine the UC's lumbar region and lower extremities while documenting that he did. Tr. 97–99. Moreover, at the fourth visit, Respondent again documented that the UC had a pain level of 5, although the transcript contains no indication that the UC was asked about his pain level by Respondent. GX 9, at 20–22. 10

Respondent further contends that the ALJ erred in concluding that he "failed to fully document his periodic

assessment and documentation of the patient's functional status, including the ability to engage in work or other purposeful activities, the interference with activities of daily living, quality of family life and social activities." Exceptions, at 7 (quoting R.D. 79, Conclusion of Law #8). Respondent asserts that Ohio law does not require "a prescribing physician to perform these measures for acute pain patients." Id. Apparently, Respondent's view is that notwithstanding that he treated each of the UCs for pain with controlled substances for "longer than three continuous months," Ohio Rev. Code § 4731.052(A)(1), he cannot be held to have violated the Ohio statute because he never actually diagnosed the patients as having chronic pain. See Resp. Post-Hrng. Br., at 7-9. ("The express language of . . . § 4731.052 requires a physician diagnosis of 'chronic pain.' The statute does not mandate a diagnosis of chronic pain, but rather is instructive as to what is required after such a diagnosis. In the present case, none of the undercover . . . Agents was diagnosed by Dr. Zaidi as having chronic pain.").

Notably, the Government's expert (who has been an expert reviewer for the state medical board) explained that at twelve weeks, Ohio law considers this to be "protracted prescribing," which requires "a much higher level of intensity of service." Tr. 100; see also id. at 285–87.<sup>11</sup> But even if it is the case that a physician can avoid having to comply with the requirements section 4731.052 imposes after three months by simply failing to make a diagnosis of chronic pain, I would still conclude that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose in prescribing to the undercover officers.

As the Government's expert explained, the prescriptions "were not for a legitimate medical purpose," Tr. 103, because the diagnosis of lumbar radiculitis "is not justified or substantiated by either the history or the physical examination." *Id.* at 107; *see also id.* at 268 (expert finding "no

<sup>&</sup>lt;sup>9</sup>Nor does the medical record contain an entry for this visit in the Nursing Progress Record (as it does for the other visits). GX 12, at 18. Respondent's signed progress note for the UC's fifth and final visit does not contain a numerical entry for his pain level; however, the Nursing Progress Record documents both the present level of his pain, and its worst level during the week as a "2." *Id.* 

<sup>&</sup>lt;sup>10</sup> The record also contains substantial evidence to support findings that Respondent failed to perform physical examinations of the two other undercover officers while documenting that he had done so, as well as that he documented that the undercover officers reported higher pain levels than they actually had. See R.D. at 79 (FoF #7).

 $<sup>^{\</sup>scriptscriptstyle{11}}\!$  As the expert testified:

That 90 days is a pause, and it is a method of communicating very forcefully to the physician, that if this is going on for that time, there better be quite a bit of substantiation behind it, and intensity of service needs to justify the continued uses of that medication. . . . It's not reasonable, especially when a patient is being seen acutely, that even we see from the emergency department with several weeks of pain, it's really not reasonable to know how long that prediction is. But what the law is saying is that if somebody needs controlled substances that long, this is the level of intensity of service that somewhere along the line, needs to have been accomplished.

Id. at 286-87.

supporting evidence" for a diagnosis of lumbar radiculitis). The expert also observed that if he had "reviewed only the medical record . . . [he] would have arrived at a different opinion" than what he did having been able "to see a transcript and watch an audio/visual recording of what actually occurred during that encounter," and that the medical record "makes it appear that the severity of the patient['s] condition is much more severe than what I'm seeing when I actually am watching and listening to the recording of the events.' Id. at 108. Given what the video recordings of the UC's visits with Respondent show, I agree. 12

Also, the expert explained that the treatment plan "focuse[d] only on controlled substances and not on other alternative approaches to care," id. at 103, such as "physical therapy" and "non-controlled" medications such as non-steroidal anti-inflammatories, neuro-modulators, and tricyclic medications. Id. at 107. And while the progress notes after the undercover officer's first visit list a "home exercise program" as part of the treatment plan, as the expert explained, there was no evidence that Respondent provided such a program to the undercover officer. Id. at 108; see also Tr. 82.

Respondent also asserts that the Government's expert applied "his own subjective interpretation of how he believed a physical examination should be conducted and diagnosis determined" and that "[t]here is no evidence in the record to establish what a physical exam or diagnosis requires.' Resp. Post-Hrng. Br., at 11. It is noted, however, that the Government's expert is board certified in anesthesiology, internal medicine, and pain medicine; that he is the Director of Pain Medicine Services and the Pain Medicine Fellowship at the Ohio State University Medical Center; that he has taught courses in Acute Pain, Chronic Pain, and Chronic Back Pain; and that he has served as an expert reviewer in pain medicine for the State Medical Board of Ohio. GX 2.

Moreover, in his testimony, the Government's expert acknowledged the 'concept described as [the] minimal standard of care," which he explained as "those actions and decisions that would be made by a reasonable physician under similar circumstances." Tr. 204. The expert then testified that in the "environment under which we discuss this case, that standard of care and the minimal standard of care can be considered one [and] the same," and that if a physician meets the minimal standard of care, he meets the standard of care. Id. at 204-05. Thus, I reject Respondent's contention that the expert applied his own subjective standard rather than the standard of a reasonable physician in concluding that Respondent acted outside the usual course of professional practice in prescribing to the undercover officers.

So too, while the expert was not asked what tests are necessary to conduct a physical examination which meets the standard of care with respect to the specific diagnoses made by Respondent, on cross-examination, the expert explained that "[r]adiculopathy and radiculitis are very similar diagnoses and [have] very similar causes, but the diagnosis of radiculopathy is a nerve injury that is a permanent loss of nerve function and that the distribution of the change in permanent function is that which corresponds to those muscles or portions of . . . the body that that particular nerve serves." *Id.* at 203–04. When then asked whether he saw "any evidence of that type of diagnosis in any of the undercover agents," the expert answered that he "did not see any evidence...of them displaying the physical findings or the complaints of a permanent nerve injury." Id. at 204. Thus, I am satisfied that substantial evidence supports a finding that Respondent's diagnosis of lumbar radiculitis with respect to two of the undercover officers was not justified by their histories and physicals.13

I therefore reject Respondent's exception to the ALJ's legal conclusion that the prescriptions were not issued for a legitimate medical purpose in the usual course of professional practice. See R.D. at 82–83 (Conclusion of Law #8); Resp. Exceptions, at 6–9.

# Exception Three—The ALJ Erred In Evaluating the Public Interest Factors

Respondent further argues that the ALJ "incorrectly determined that Factors 2, 4, and 5 support revocation" of his registration. Resp. Exceptions, at 10. While I find that some of Respondent's contentions are well taken, I conclude that the record as a whole supports the ALJ's ultimate conclusions that Respondent has committed such acts as to render his registration inconsistent with the public interest (had he submitted an application), and that Respondent failed to rebut this conclusion. R.D. at 87.

As this Agency has long held, I am not required to make findings under each of the factors and findings under a single factor are sufficient to support the revocation or suspension of a registration. See Hoxie v. DEA, 419 F.3d, 477 482 (6th Cir. 2005); Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005). In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest.

With respect to factor two—Respondent's experience in dispensing controlled substances—Respondent argues that the Government seized more than 400 patient files from his office "and failed to present any evidence . . . that the treatment of those patients failed to meet the standard of care." Resp. Exceptions, at 10. He also argues that "there were over 400 additional patients' charts which were not seized and [that] no evidence was presented to question their treatment." *Id.* Respondent thus contends that in this matter, "there was no attempt at 'fair adjudication." *Id.* The Agency has repeatedly rejected

The Agency has repeatedly rejected Respondent's contention. See, e.g., Jayam Krishna-Iyer, 74 FR 459, 463

<sup>12</sup> For example, at the UC's first visit, Respondent's physical examination was limited to asking the UC to stand up, turn around and show him where the pain was; having the UC bend forward and come back up; and then having the UC walk on his heels, turn, and walk on his toes. GX 3a. The entire encounter between Respondent and the UC lasted four minutes and resulted in Respondent writing a prescription for Percocet. *Id.* 

During the UC's subsequent four visits, Respondent never performed a physical exam, while documenting having done so. See GX3b, c, d, and e. Moreover, the UC's encounters with Respondent lasted between three minutes and thirty seconds (3'30") at the second visit and one minute and twenty seconds (1'20") at the fifth visit. See id.

<sup>&</sup>lt;sup>13</sup> While I have discussed the expert's testimony in addressing Respondent's Exceptions, as stated above, the recordings which show that Respondent falsified the medical records with respect to both the scope of the examinations he performed and the UCs' reported pain levels, the briefness of the encounters, and his refusal to testify, provide sufficient evidence, apart from the expert's testimony, to support a finding that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed to the UCs. See United States v. Pellman, 668 F.3d 918, 924 (7th Cir. 2012) (quoting *United* States v. Armstrong, 550 F.3d 382, 389 (5th Cir. 2008) ("While expert testimony may be both permissible and useful, a jury can reasonably find that a doctor prescribed controlled substances not in the usual course of professional practice or for other than a legitimate medical purpose from adequate lay witness evidence surrounding the facts and circumstances of the prescriptions."));

Armstrong, 550 F.3d at 389 ("Jurors have had a wide variety of their own experiences in doctors' care over their lives, thus . . . expert testimony is not necessarily required for jurors to rationally conclude that seeing patients for as little as two or three minutes before prescribing powerful narcotics is not in the usual course of professional practice.")). See also T.J. McNichol, 77 FR 57133, 57147 (2012) (discussing both judicial and administrative cases); Jack A. Danton, 76 FR 60900, 60901 (2011).

(2009). In Krishna-Iyer, a case in which the Government relied solely on evidence of the physician's unlawful prescribing to several confidential sources, the Agency assumed that the physician's prescribing to 12 patients whose files were seized but were not relied on by the Government in presenting its case, as well as thousands of other patients (other than the undercover operatives), constituted evidence of dispensing controlled substances in circumstances which did not constitute diversion. Id.

However, as the Agency explained, the physician's "prescribings to thousands of other patients do not . . . render her prescribings to the undercover officers any less unlawful, or any less acts which are 'inconsistent with the public interest.'" *Id.* The Agency further explained that:

under the CSA, a practitioner is not entitled to a registration unless she "is authorized to dispense . . . controlled substances under the laws of the State in which [she] practices." 21 U.S.C. 823(f). Because under law, registration is limited to those who have authority to dispense controlled substances in the course of professional practice, and patients with legitimate medical conditions routinely seek treatment from licensed medical professionals, every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of her professional career. Thus, in past cases, this Agency has given no more than nominal weight to a practitioner's evidence that he has dispensed controlled substances to thousands of patients in circumstances which did not involve diversion.

Id. (citations omitted); see also Medicine Shoppe-Jonesborough, 73 FR 364, 386 & n.56 (2008) (even though pharmacy "had 17,000 patients," "[n]o amount of legitimate dispensings" could render the pharmacy's "flagrant violations [acts which are] 'consistent with the public interest'"), aff'd, Medicine Shoppe-Jonesborough v. DEA, 300 Fed. Appx. 409 (6th Cir. 2008).

Accordingly, in Krishna-Iyer, the Agency held that "evidence that a practitioner has treated thousands of patients [without violating the CSA] does not negate a prima facie showing that a practitioner has committed acts inconsistent with the public interest." 74 FR at 463. The Agency thus explained that "[w]hile such evidence may be of some weight in assessing whether a practitioner has credibly shown that she has reformed her practices, where a practitioner commits intentional acts of diversion and insists she did nothing wrong, such evidence is entitled to no weight." *Id.*Subsequent to *Krishna-Iyer*, the

Subsequent to *Krishna-Iyer*, the Agency adhered to this rule in *Dewey C. MacKay*, 75 FR 49956 (2010), *pet. for* 

rev. denied, MacKay v. DEA, 664 F.3d 808 (10th Cir. 2011). Based on the substantial evidence that the physician had knowingly diverted controlled substances to two patients who acted in an undercover capacity, the Agency held that the Government had satisfied its prima facie burden of showing that Respondent had committed acts which rendered his registration inconsistent with the public interest. 75 FR 49977.

The Agency also addressed and rejected the physician's contention that "[a] better assessment of [his] medical practice and habits can be ascertained from [his] numerous positive experiences in prescribing controlled substances, some of which were recounted by the patients themselves . . at the hearing." Id. (quoting Resp. Br. at 3). As the Agency explained: "even assuming, without deciding, that Respondent's prescribing practices to all of his other patients (including those whose medical records were reviewed by the Government's expert but who did not perform undercover visits 14) fully complied with the CSA and Utah law, these prescribings do not refute the evidence showing that he intentionally diverted to [the two undercovers] in violation of both the CSA and Utah law." 75 FR at 49977. Noting that the physician had failed to testify and offer evidence that he recognized the extent of his misconduct and was prepared to remedy his unlawful practices, the Agency revoked his registration.

The Tenth Circuit denied the physician's petition for review. *MacKay* v. *DEA*, 664 F.3d 808 (10th Cir. 2011). Of relevance here, the Tenth Circuit specifically addressed and rejected the physician's argument that the Agency had failed to consider his "positive experience" in dispensing controlled substances to other patients. As the Court of Appeals explained:

Despite Dr. MacKay's claim to the contrary, the Deputy Administrator considered the entire record, including the evidence in Dr. MacKay's favor. She determined, however, that none of Dr. MacKay's evidence negated the DEA's prima facie showing that Dr. MacKay had intentionally diverted drugs to K.D. and M.R. Indeed, she found that even if Dr. MacKay had provided proper medical care to all of his other patients, that fact would not overcome the government's evidence with regard to M.R. and K.D.

None of the evidence presented by Dr. MacKay undermines the evidence relating to M.R. and K.D. Although numerous patients and colleagues of Dr. MacKay related their positive experiences with him, none had any personal knowledge regarding his treatment

of M.R. and K.R. Notably, Dr. MacKay's medical expert, Dr. Fine, failed to specifically discuss and justify Dr. MacKay's treatment of M.R. and K.D. As a result, none of Dr. MacKay's evidence contradicts the testimony and evidence presented by the DEA relating to the knowing diversion of drugs to these two patients.

664 F.3d at 819.

The Court of Appeals thus concluded that "[a]lthough Dr. MacKay may have engaged in the legitimate practice of pain medicine for many of his patients, the conduct found by the Deputy Administrator with respect to K.D. and M.R. is sufficient to support her determination that his continued registration is inconsistent with the public interest." *Id.* 

In this matter, I have assumed that Respondent lawfully complied with the CSA whenever he prescribed controlled substances to all of his patients (including the 800 patients with respect to whom no evidence was offered) other than the undercover officers. 15 But even assuming that Respondent lawfully prescribed controlled substances to all of these other patients, the evidence still supports a finding that he knowingly and intentionally diverted controlled substances to the undercover officers. 16 This finding is relevant in assessing both his experience in dispensing controlled substances (factor two) and his compliance with applicable laws related to controlled substances (factor

Given that Respondent was the only doctor at the clinic, there is no need to decide whether the evidence establishes the existence of such a protocol (whether written or not) or whether such 'operations' were established. As the evidence shows, Respondent repeatedly failed to perform physical examinations (or performed inadequate exams) and then falsified the undercover officers medical records to reflect his having performed such exams; he also falsified the medical records by documenting higher pain levels than those reported by the undercover officers. As explained above, this evidence establishes that Respondent knowingly diverted controlled substances. Indeed, the ALJ specifically found that Respondent violated 21 CFR 1306.04(a) when he issued prescriptions that lacked "a legitimate medical . . . purpose and were not written in the ordinary course of [his] professional practice." R.D. 83. I therefore reject it.

<sup>&</sup>lt;sup>14</sup> In light of the evidence provided by the undercover visits of the two patients, the Agency found it unnecessary to make any findings based on the expert's chart review. 75 FR 49972.

<sup>&</sup>lt;sup>15</sup>This is not a case in which there is any ambiguity as to Respondent's intent when he prescribed controlled substances to the undercover officers. Thus, evidence of his lawful prescribings to others would not lead any reasonable factfinder to conclude that he acted within the usual course of professional practice when he prescribed to the undercover officers.

<sup>&</sup>lt;sup>16</sup> In his decision, the ALJ also observed that Respondent's "decision to manage a pain clinic using a protocol that permitted the issuance of prescriptions for controlled substances without conducting physical examinations threatens the public safety. Either through ignorance or deliberate indifference, [his] decision to establish such operations indicates he lacks sufficient insight and experience to be trusted to participate in the controlled substances distribution process." R.D. at <sup>50</sup>–51

four), and by itself, it is sufficient to satisfy the Government's *prima facie* burden of showing that Respondent "has committed such acts as would render his registration . . . inconsistent with the public interest." <sup>17</sup>

17 Respondent also takes exception to the ALJ's finding that he did not adequately address various red flags presented by the undercover officers. Resp. Exceptions, at 11–12. Among the red flags cited by the ALJ were the UCs requesting specific drugs such as OxyContin, Percocet, and Opana, which are highly diverted; the UCs seeking increases in the quantities of the prescriptions; a UC being unable to produce his driver's license; a UC's report of having obtained medication from his wife; and the UCs' non-compliance with Respondent's recommendations that they obtain MRIs or receive cortisone injections. R.D. at 79–80.

Respondent notes that when the undercover officer posing as Patrick Tock requested that he be prescribed Opana (because a friend had said it worked for him), Respondent warned him about the dangers of the drug and did not prescribe the drug. Resp. Exceptions, at 11. Respondent further notes the testimony of the Government's expert that Respondent's decision not to prescribe the medication was appropriate. *Id.* (citing Tr. 200). Moreover, in other instances, the Government's expert conceded that Respondent could properly take into consideration a patient's ability to pay for a test or procedure. Respondent thus contends that the ALJ's finding "ignores the undisputed evidence" and was arbitrary and capricious. *Id.* 

While I agree with the ALI's reasoning that "[a] practitioner's failure to resolve red flags strongly suggests that the practitioner's subsequent dispensation of controlled substances to that patient is not for a legitimate medical purpose," R.D. at 60, this is so because such evidence is probative of the physician's knowledge or intent. However, in this matter, there is no need to resolve the issue of whether Respondent adequately addressed various red flags. This is so because the evidence that: 1) Respondent failed to performed physical exams (as well as various tests as part of the physical exams) yet falsified the medical records by documenting that he did, 2) falsified the medical records to reflect higher pain levels than those actually reported by the undercover officers, as well as 3) the adverse inference to be drawn from his refusal to testify, conclusively prove that Respondent acted outside the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to the undercover officers and thus knowingly diverted controlled substances.

Thus, to the extent Respondent failed to address any red flags, this is simply additional evidence probative of the illegality of the prescriptions. See United States v. Moore, 423 U.S. 122, 142-43 (1975). Proof that a physician knowingly diverted controlled substances is the best evidence for assessing his experience in dispensing controlled substances, although it is also relevant in assessing his compliance with applicable laws related to controlled substances. However, while such evidence is relevant under both factors two and four, in making the public interest determination, the Agency does not adjudicate the case by mechanically counting up the number of factors that favor each party and declare a winner. Rather, consistent with the statute, the Agency's inquiry focuses on whether the registrant "has committed such acts as would render his registration. inconsistent with the public interest." 21 U.S.C. 824(a)(4). Thus, what matters is the egregiousness of the proven misconduct, the need to deter future noncompliance by both the specific registrant and the community of registrants, and the registrant's evidence of remediation and acceptance of responsibility.

With respect to factor four, Respondent contends that the ALI took a "quantum leap" when he found "that Respondent intentionally kept inconsistent medical records on [the UC's pain levels in order to protect himself from an audit." Resp. Exceptions, at 13 (citing R.D. 66). According to Respondent, "[i]t defies logic to believe that [he] would attempt to intentionally create a false medical record by increasing a pain level from 3 to 4 or 5 on a 1-10 scale, especially knowing the chart accurately contains references to [the] pain levels communicated by the DEA agent," which are still "in the same moderate range." Id.

It is true that the undercover officers' charts contain a nursing progress record which accurately reflects what they reported to Respondent's medical assistant. That being said, Respondent does not challenge the ALJ's findings that he falsified the medical records by documenting having performed various tests as part of a physical examination which he failed to do. Based on this evidence, as well as Respondent's refusal to testify and explain the disparity in the pain levels, I draw the same inference that the ALJ did-that the pain levels were falsified (along with the results of physical examinations he did not perform) to provide documentation to support the prescriptions. 18 I therefore reject Respondent's exception.

Respondent's diversion of controlled substances is properly considered as evidence of his lack of compliance with applicable laws related to controlled substances. So too, his failure to comply with Ohio's regulation which requires that "[a] physician shall complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients," Ohio Admin. Code § 4731–11–02(D), is also relevant in assessing his compliance with applicable laws related to controlled wheteness 19

substances.19

# Exception Four—The ALJ's Recommended Order of Revocation is not Warranted

While merged with his exception to the ALJ's factor five analysis, Respondent also takes exception to the ALJ's recommended order of revocation, arguing that this sanction "is unwarranted in law and without justification in fact." Resp. Exceptions, at 16. He further asserts—notwithstanding his refusal to testify—that he "has accepted responsibility for

activities to law enforcement authorities" and that she and Respondent "never talked about it." R.D. at 74. The ALJ then opined that:

a strong argument can be made for the proposition that [Respondent's] failure to correctly understand the law enforcement exceptions to HIPAA and to discuss with his staff the role law enforcement plays in preventing abuse and diversion is important. If pain management staff members observe evidence of doctor shopping or diversion of prescribed narcotics, those staff members should be familiar with steps they can and must take to alert the relevant authorities of possible illicit action. [Respondent] is responsible for ensuring that his staff understands the practitioner's role in preventing abuse and diversion of controlled substances.

Id. at 75–76. The ALJ then found that Respondent's "office practice generally created a risk to the public safety in failing to properly train his staff regarding the role of law enforcement officers in detecting abuse and diversion of controlled substances." Id.

Respondent takes exception to the ALJ's findings and legal conclusions, noting that while the "HIPAA provides certain law enforcement exceptions to the confidentiality of protected health information, there is no provision in HIPAA that requires an office practice to report 'doctor shopping' to law enforcement." Resp. Exceptions, at 15. Respondent further notes that "[i]n this case, there is not even any evidence of 'doctor shopping.'" Id.

I agree with Respondent that the HIPAA does not require such reporting (as well as that there is no evidence of doctor shopping in this case). Moreover, in this case, there is no evidence that either Ohio law or the standards of professional practice require a doctor to report a doctor shopper to law enforcement, and there may be valid reasons why a physician, who acts entirely within the bounds of both the law and the standards of professional practice, would take issue with the notion that his/her employees should report instances of doctor shopping to the authorities rather than to him or herself.

Accordingly, I reject the ALJ's reasoning. I also reject his finding of fact number twelve, to the extent it states that Respondent "did not provide training to his staff regarding exceptions to patient privacy laws that apply when the staff members observe behavior relating to controlled substance abuse, misuse, or diversion," R.D. at 80, as well as his conclusion of law number thirteen. *Id.* at 86 (concluding that Respondent's "actions or omissions" constitute "other conduct which may threaten public health and safety" because he "failed to provide training to his staff regarding exceptions to patient privacy laws that apply when staff members observe behavior relating to controlled substance abuse, misuse, or diversion").

While I reject the ALJ's finding and conclusion of law on this issue, I agree with the ALJ's finding that the pre-signing of prescriptions, even if there is no proof that the prescriptions were issued on a subsequent day, constitutes conduct which may threaten public health and safety.

<sup>&</sup>lt;sup>18</sup> Contrary to Respondent, it does not necessarily defy logic to conclude that he intentionally falsified the record by listing a higher pain level than that documented by his medical assistant in the nursing progress record. Respondent may not have even bothered to read the nursing progress record.

<sup>&</sup>lt;sup>19</sup> With respect to factor five, the Government argued that Respondent "maintained policies [that] were contrary to Federal law," in that his "employees were forbidden from contacting law enforcement in the event they suspected patients were obtaining multiple prescriptions for controlled substances from multiple doctors." Gov. Post-Hrng. Br., at 26. While the ALJ found that the evidence did not support the existence of such a policy, he then noted that one of Respondent's employees testified that she "felt that laws regarding patient privacy prohibited her from reporting patient

his recordkeeping issues" and that "[t]hrough his counsel, [he] states that he is willing, if given the opportunity, to remediate these issues in order to avoid future misconduct." Id. This issue, however, is rendered moot by Respondent's failure to file a renewal application. See Darryl J. Mohr, 77 FR 34998, 34999 (2012) ("While this Agency has recognized that because an immediate suspension order involves the exercise of summary process, it is reviewable in a proceeding under 21 U.S.C. 824, even where collateral consequences exist, review of the order is limited to challenging its factual and legal basis. Whether a former registrant has accepted responsibility for his misconduct has no bearing on the validity of the suspension order.").

#### Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I affirm the Order of Immediate Suspension of DEA Certificate of Registration BA3842259, issued to Syed Jawed Akhtar-Zaidi, M.D. Also, pursuant to the authority vested in me by 21 U.S.C. 824(f), I further order that all right, title, and interest in the controlled substances seized by the Government during the execution of the Order of Immediate Suspension be, and hereby is, vested in the United States.<sup>20</sup>

Dated: July 13, 2015.

#### Chuck Rosenberg,

Acting Administrator.

Frank W. Mann, Esq., for the Government Walter F. Ehrnfelt, Esq., for the Respondent

#### RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

#### Nature of the Case

Administrative Law Judge Christopher B. McNeil. These are proceedings before the Drug Enforcement Administration and the United States Department of Justice, under docket number 14–2, captioned In the Matter of Syed Akhtar-Zaidi, M.D. The proceedings are being held pursuant to sections 303 and 304 of the Controlled Substances Act, Title 21 United States Code sections 823 and 824.

On October 8, 2013, the Drug Enforcement Administrator through her Deputy Administrator issued an order to show cause why the Administrator should not revoke DEA Certificate of Registration number BA3842259, issued to Syed Jawed Akhtar-Zaidi, M.D., and should not deny any application for renewal or modification of the same. <sup>1</sup> That certificate authorizes distribution of controlled substances out of an office located at 34055 Solon Road, Suite 201, Solon, Ohio 44139. <sup>2</sup> The order also immediately suspended this DEA registration, under the authority found in 21 CFR 1301.36(e) and 1301.37(c).

In the order, the Deputy Administrator alleged that Dr. Zaidi's continued registration is inconsistent with the public interest, in that between September 2012 and May 2013, Dr. Zaidi distributed controlled substances by issuing prescriptions under conditions that fell outside the usual course of professional practice or were for other than legitimate medical purposes.<sup>3</sup> Further, the Administrator determined that based on reports presented to her, Dr. Zaidi's continued DEA registration constitutes an imminent danger to the public health and safety, warranting the immediate suspension of Dr. Zaidi's registration, which is to remain in effect until a final determination is reached in these proceedings.4

On October 23, 2013, the Office of Administrative Law Judges for the DEA received Respondent's Request for a Hearing to determine whether Dr. Zaidi's continued registration would be consistent with the public interest.<sup>5</sup>

I granted Respondent's request for a hearing, and in advance of the hearing I asked the parties to offer prehearing statements that included summaries of proposed testimony along with proposed stipulations of fact, with the Government being directed to file their proposal by November 19, 2013, and Respondent by November 26, 2013. I also set the matter for hearing to commence on December 10, 2013, with non-testimonial presentations to be held at the DEA's hearing facility in Arlington, Virginia, and with testimony to be taken during the week beginning January 6, 2014, in Cleveland, Ohio.<sup>6</sup>

On November 6, 2013 I received the parties' consent motion to accelerate the hearing. 7 Upon this motion on November 6, 2013, I ordered the testimonial hearing to begin on

December 16, 2013, in Cleveland, and retained all other procedural deadlines.<sup>8</sup>

On December 10, 2013, the initial day of the hearing, federal offices were closed due to winter weather, and I ordered the cancelation of the initial day of hearing. Upon Respondent's request, a prehearing telephone conference was held on December 12, 2013, in order to address pending procedural issues. Upon Respondent's request.

At that time I had before me the Government's motion for an order in limine and Respondent's motion to delay the evidentiary hearing scheduled to begin four days later. 11 The core premise relied upon by the Government in support of its motion was Respondent's failure to timely comply with the procedural orders set forth in my prehearing order of October 24, 2013, particularly with respect to the failure to timely identify Respondent's expert witness and the substance of his testimony, and Respondent's failure to provide sufficient descriptions of expected testimony. 12 Further, the Government argued that witness descriptions provided by Respondent's prehearing statement indicate the proposed testimony would be irrelevant or otherwise inadmissible. 13

Respondent, on the other hand, sought to delay the hearing in order to accommodate his expert witness, whom he described as having medical problems that prevented his appearance on December 16 or 17, 2013.<sup>14</sup>

During the prehearing teleconference on December 12, 2013, I denied Respondent's renewed motion to delay the hearing, finding cause had not been shown to require a delay in the testimonial segment of this proceeding. Respondent first sought to delay the hearing on November 25, 2013, the day before prehearing statements were due, in order to have "adequate time to prepare," citing the difficulties in doing so occasioned by the Government's "prehearing seizure of effectively all of Respondent's liquid assets." 15 I considered the balancing of convenience to the litigants, witnesses, counsel, and the Office of Administrative Law Judges, the complexity of the case, and whether denial of the request would result in

<sup>&</sup>lt;sup>20</sup> For the same reasons that led me to immediately suspend Respondent's registration, I conclude that this Order should be effective immediately. 21 CFR 1316.67.

<sup>&</sup>lt;sup>1</sup> ALJ Ex. One at 1.

<sup>&</sup>lt;sup>2</sup> Gov't Ex. One.

<sup>&</sup>lt;sup>3</sup> ALJ Ex. One at 1-3.

<sup>4</sup> Id. at 4.

<sup>&</sup>lt;sup>5</sup> ALJ Ex. Two at 1.

<sup>&</sup>lt;sup>6</sup> ALJ Ex. Three.

<sup>&</sup>lt;sup>7</sup> ALJ Ex. Five

<sup>&</sup>lt;sup>8</sup> ALJ Ex. Six.

<sup>9</sup> ALÍ Ex. 21.

<sup>10</sup> ALJ Ex. 24.

<sup>&</sup>lt;sup>11</sup> See ALJ Exs. 22 & 20.

<sup>&</sup>lt;sup>12</sup> ALJ Ex. 20.

<sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> ALJ Ex. 22.

<sup>15</sup> ALJ Ex. Nine.

identifiable prejudice to Respondent. 16 Upon considering these factors I found cause had not been shown to delay either the scheduled hearing or the prehearing deadlines.

I received Respondent's second request to delay the hearing on December 6, 2013.<sup>17</sup> This was based on the representation that an expert witness, Richard Stieg, M.D., would be unavailable on the dates set for hearing.18 I considered the factors set forth above, and found cause had not been shown to delay the hearing in an order dated December 6, 2013.19 On December 12, 2013, I received Respondent's motion for reconsideration of the order denying Respondent's second requested continuance.<sup>20</sup> In denying the motion during the prehearing teleconference, I considered the premises presented in support of the motion, including the premise that the continuance was needed to permit Respondent's medical expert to testify.

İn reviewing Respondent's prehearing statement and each supplement thereto, I found that the proposed expert witness's testimony as summarized by Respondent did not need to be presented at the same time as the rest of the testimony being offered, and could be taken out of order without prejudice to Respondent. I further found that the evidence would likely have little probative value, as the witness did not appear to be familiar with Ohio medical practice standards. I also considered the uncertain nature of the length of the delay that would be needed to accommodate Dr. Stieg.

Additionally, I considered the potential adverse effects of such an uncertain delay in resolving this matter. In this regard I am guided by the expectation that where doing so is not inconsistent with a litigant's rights under the Due Process Clause or the Administrative Procedure Act, I should endeavor to submit the certified record of these proceedings to the Administrator in accordance with 21 CFR 1316.65 not later than the 150th day after the issuance of an immediate suspension (excepting any days caused by Respondent's own actions).<sup>21</sup> I also considered the possible prejudice to either party were the hearing to proceed

as scheduled, and found no substantial prejudice had been demonstrated. I also considered the potential importance of the testimony being sought, should a delay be granted. Upon weighing these factors and exercising the discretion delegated to me,22 I found cause had not been shown to delay the testimonial portion of this proceeding. I also permitted Respondent to proffer the medical expert's report for the Administrator's review, so that the hearing could proceed expeditiously while allowing Respondent to present the substance of that report to the Administrator, for her consideration.

Further, I granted the Government's motion for an order in limine, finding the proffer of testimony presented with respect to witnesses Elizabeth and Larry Bloch, Patricia Grav, Carolyn Hamilton, Beverly and Virgil Humphreys, James Justice, Greg Ratesic, Lorinda Rose, and Carl Shortridge was insufficient to establish that their testimony would be relevant to the issues before me. I found Respondent's proffer of testimony from his employees Christi Barrett, Julie Brzozwski, and Ricki Zotto was untimely and was insufficient to establish that their testimony would be relevant, and for those reasons I sustained the motion with respect to those three witnesses. I noted that Respondent's employee, Kim Maniglia, was identified as a Government witness and determined that there was no reason to bar her from testifying on behalf of Respondent.

With respect to testimony from Respondent's expert, I found sufficient prejudice had been shown by the Government to sustain its motion and bar the testimony of Dr. Stieg, due to the untimely disclosure of the identity of the expert and the nature of his testimony, and due to the lack of detail in the description of the proposed testimony, including the description presented in Respondent's December 12, 2013 supplemental prehearing

statement.

Regarding the lack of specificity and detail provided regarding Respondent's own testimony, I found Respondent's prehearing statement did not comply with my prehearing order in that it did not indicate clearly each and every matter as to which he intended to testify. While cause had been shown to bar Respondent's testimony, the Government did not seek to bar Respondent from testifying but instead sought to have Respondent supply the required summary prior to the conclusion of the first day of hearing,

which had been scheduled for December 10, 2013.23 Although I found sufficient cause including clear prejudice to the Government due to Respondent's failure to comply with my prehearing order, Respondent was not barred from testifying but his testimony was limited to responding to the areas of inquiry presented in the Government's prehearing statement along with any areas set forth in a more complete summary which I allowed to be filed by not later than 2 p.m. on Friday, December 13, 2013. Although Respondent filed a "Brief in Opposition to the Government's Motion in Limine" describing testimony he would elicit from other witnesses,<sup>24</sup> he provided no supplemental statement describing the scope of his own testimony.

When the parties convened in Cleveland for the testimonial portion of the hearing, acting on the advice of his attorney, Dr. Zaidi exercised his constitutional right against compulsory self-incrimination and, after being sworn and identifying himself, declined to answer questions presented to him on direct examination by the Government.<sup>25</sup> The Government presented the testimony of its medical expert, four investigative witnesses, and Dr. Zaidi's billing clerk. Dr. Zaidi presented no testimony, but offered documents which have been identified as proffers and have been included in the record for the Administrator's review. I did not, however, consider Respondent's proffered exhibits in reaching my Recommended Decision.

#### **Summary of the Evidence**

The Government's case was presented through testimony of three undercover agents who posed as patients; Dr. Zaidi's billing clerk, Kim Maniglia; Diversion Investigator Scott A. Brinks; and Steven Severyn, M.D., who testified as the Government's medical expert.26

#### Testimony of the Government's Medical **Expert**

Dr. Severyn practices medicine at the Comprehensive Spine Center located at The Ohio State University Wexner Medical Center, in Columbus, Ohio.<sup>27</sup> He is licensed to practice medicine in Ohio, and serves as the Director of the Pain Medicine Services office of the Medical Center's Department of Anesthesiology, the Director of the Medical Center's Pain Medicine Fellowship, and the Director of the Pain

<sup>&</sup>lt;sup>16</sup> See Fitzhugh v. Drug Enforcement Administration, 813 F.2d 1248, 1252 (D.C. Cir.

<sup>&</sup>lt;sup>17</sup> ALJ Ex. Seventeen.

<sup>&</sup>lt;sup>18</sup> Id.

<sup>&</sup>lt;sup>19</sup> ALJ Ex. Eighteen.

<sup>&</sup>lt;sup>20</sup> ALI Ex. 22.

<sup>&</sup>lt;sup>21</sup> See Memorandum re: Immediate Suspension of DEA Registration; Hearing Process DFN: 301-01, October 4, 2006 at 1 (copy attached as Appendix).

<sup>&</sup>lt;sup>22</sup> See Richard A. Herbert, M.D., 76 FR 53942-02, 53942 (DEA Aug. 30, 2011).

<sup>&</sup>lt;sup>23</sup> ALJ Ex. 20 at 7.

<sup>&</sup>lt;sup>24</sup> ALJ Ex. 25.

<sup>25</sup> Tr. at 50.

<sup>26</sup> Id. at 51.

<sup>27</sup> Id. at 52.

Services section of the Spine Center.<sup>28</sup> He is an assistant professor of clinical anesthesiology, teaching on almost a daily basis in clinical and educational capacities, and practices in the Spine Center and throughout the hospitals of The Ohio State University.<sup>29</sup> He estimated that 50 percent to two-thirds of the patients he treats for pain are prescribed controlled substances for that pain.30

Dr. Severyn holds a baccalaureate degree from Johns Hopkins University, a medical degree from The Ohio State University, a master's degree in business administration from Ohio University, and a master's degree in strategic studies at the United States Army War College.<sup>31</sup> He completed an internal medicine residency at Riverside Methodist Hospital, as well as a residency in anesthesiology at The Ohio State University.32 He holds board certifications with the American Board of Internal Medicine, the American Board of Anesthesiology, and that Board's pain medicine subspecialty.33

In his current medical practice, Dr. Severyn works full time in the subspecialty of pain medicine.34 He stated that on a typical clinical day he will encounter approximately 30 patients, and on a typical surgical day he will perform between three and six operative procedures.<sup>35</sup> He explained that his patients predominantly are persons without cancer-related diagnoses who are seen on an out-patient basis and are experiencing acute and chronic intractable pain, although some are treated on an in-patient basis for postoperative pain.36

Dr. Severyn stated that he has been qualified in the past as an expert witness in matters concerning the evaluation and treatment of patients using controlled substances, for both the DEA and the United States Department of Justice.<sup>37</sup> Without objection, Dr. Severyn was recognized as an expert in the field of pain management in these proceedings.38

In preparing to testify in this matter, Dr. Severyn reviewed video recordings of interactions between undercover agents Parkison, Leonard, and Moses. and Dr. Zaidi.39 He also read the

28 Id. at 52-53.

transcripts from those interactions, and the medical records maintained by Dr. Zaidi regarding the treatment of these three patients. 40 In his review, Dr. Severyn applied his understanding of provisions in Ohio law, including section 4731-21-02 of the Ohio Administrative Code, regarding the treatment of intractable chronic pain.41 Based on this review and applying his understanding of the requirements for the treatment of pain using controlled substances applicable in Ohio, Dr. Severyn concluded that Dr. Zaidi prescribed controlled substances to each of these patients outside the usual course of professional practice 42 and for other than a legitimate medical purpose.43

In reaching these conclusions, Dr. Severyn noted the requirements found in the Ohio Administrative Code regarding the use of controlled substances for the treatment of pain.44 According to Dr. Severyn,

When selecting a treatment for a patient, the first principle is evaluation, establishing of a diagnosis, the considering of alternative treatments in making a recommendation to a patient [in] regard to treatment, a provision of the risk of each of those alternatives, and then the treating of the patients in a way that conforms with current professional standards of care.45

Further, he stated that one part of the professional standard of care for such providers is that when prescribing controlled substances for the treatment of pain, a provider must take into account the medication's potential for diversion and abuse.46 In addition, in those cases where controlled substances are being considered as part of the treatment plan, "the standard of care, and the prevailing practice of physicians, is to perform a diligent and a very sophisticated and intense evaluation." 47 In this context, Dr. Severyn stated that the minimal standard of care would be "those actions and decisions that would be made by a reasonable physician under similar circumstances." 48 "It establishes," according to Dr. Severyn, "what would be the least degree of response or establishes the least degree of care in the provision of treatment, when a physician is faced with a clinical decision, resulting in action or

inaction" and equals the minimal standard of care.49

Dr. Severyn noted that when referring to the minimal standard of care throughout his testimony, he regards this as describing the standard of care for pain medicine physicians.<sup>50</sup> He noted further that his own practice differs from many pain medicine practices because his patients all have been referred to his clinic by other medical providers in the OSU health care system.<sup>51</sup> In this respect, Dr. Severyn distinguished what a reasonable physician would do at the initial appointment from what he does in his own practice, because in the initial appointment stage of his own practice all of his patients are either referred by other OSU medical offices or have recently undergone emergency treatment.52

Beyond this, however, Dr. Severyn stated that in a pain medicine practice, there are "additional requirements for the specificity and the degree of detail in keeping medical records when prescribing controlled substances on a protracted basis, greater than twelve weeks," calculated from the initial prescribing encounter.53 He said, however, that there is no federal or state law that defines the types or amounts of drugs that should be prescribed in any particular situation—that this is a decision to be made by the doctor.54 That decision, according to Dr. Severyn, is to be based on "[e]xpertise, experience, intensity of service, diligence of work, assessment of the situation, integration of all available information, previous red flags [and] current events." 55

Dr. Severyn explained that before a physician may prescribe controlled substances for pain, he or she must reach a medical diagnosis and determine the appropriate treatment plan.<sup>56</sup> In the treatment plan, the physician and patient interact, "availing themselves of alternative approaches for care, and will go about certain actions" regarding both procedures and medication, which may then "be reevaluated at a later time, so as to determine the efficacy of the original plan." 57

Such a treatment plan would need to include "regular follow up and monitoring, not only of the patient

<sup>29</sup> Id. at 53-54, 58-59.

<sup>30</sup> Id. at 166.

<sup>31</sup> Id. at 54. 32 Id.

<sup>33</sup> Id. at 56.

<sup>34</sup> Id. at 55.

<sup>35</sup> Id. at 58.

<sup>36</sup> Id. at 55.

<sup>37</sup> Id. at 60. 38 Id. at 61.

<sup>&</sup>lt;sup>39</sup> Id.

<sup>40</sup> Id. at 61-62.

<sup>41</sup> Id. at 167.

<sup>42</sup> Id. at 104, 130, 153.

<sup>43</sup> Id. at 103, 130, 153.

<sup>44</sup> Id. at 62.

<sup>45</sup> Id

<sup>46</sup> Id. at 63.

<sup>47</sup> Id. at 65.

<sup>48</sup> Id. at 204.

<sup>49</sup> Id. at 204-05.

<sup>&</sup>lt;sup>50</sup> Id. at 205.

<sup>51</sup> Id. at 263.

<sup>53</sup> Id. at 64, 256.

<sup>54</sup> Id. at 206. 55 Id. at 207.

<sup>&</sup>lt;sup>56</sup> *Id.* at 65.

<sup>57</sup> Id. at 65-66.

condition, but also of the response to treatment." <sup>58</sup> Monitoring in this context is performed through "medical encounters, history, physical, imaging studies, social history, family history, response to medications, and it takes time to develop that, and also, attention to other details, accuracies, and any unusual events that are occurring," along with reviewing the OARRS report. <sup>59</sup> The resulting plan "needs to include the thought processes of the physician" in order to fulfill "the physician's fiduciary responsibility to the patient." <sup>60</sup>

In those cases where a physician in Ohio prescribes controlled substances for pain on a protracted basis, which in this case means for greater than twelve weeks, Dr. Severyn said that the physician must obtain the patient's consent and inform the patient of the risks and benefits associated with such a treatment plan.<sup>61</sup> Dr. Severyn said the consent needs to be in writing and needs to reflect that the physician has educated the patient "as to the nature of the condition, makes a recommendation about the approach for care, describes the risks of each of those alternatives, describes the benefits of each[,] and . explores alternative approaches." 62 Also in cases where treatment is on a protracted basis, the physician needs to assess the patient's functional status, which includes determining how the pain is interfering with the patient's ability to work, with activities of daily living, with social activities, and with the quality of family life.63

Dr. Severyn agreed with the proposition, presented during cross examination, that it will sometimes take a period of time and a number of visits for a physician to observe and evaluate a patient with respect to red flags associated with controlled substance diversion, misuse, or addiction.<sup>64</sup> When asked about the length of time Dr. Zaidi spent monitoring the progress of the cases of the three undercover agents, Dr. Severyn opined that the five or six months spent was a "moderate" amount of time. 65 He also explained that while the DEA maintains on its Web site a list of relevant red flags, he personally was "not familiar enough with that Web site and each and every flag, for me to say that I'm going to use that as my only

standard." <sup>66</sup> He added, however, that the "Web site does contain a number of causes for a physician to be suspic[ious] that the seeking of the medication may not be strictly for the treatment of the condition for which the physician intends to prescribe." <sup>67</sup>

When asked whether he believes community-based pain management clinics (i.e., clinics not in an academic setting) have a place in medicine and serve a legitimate purpose, Dr. Severvn said they certainly do have a role.<sup>68</sup> He also agreed with the proposition, asked during cross examination, that the patient's ability to pay "does have more relevance now than it did in the past few years, in the informing of a physician's recommendation or offer of care to the patient." 69 When asked. however, whether he would dismiss a patient who elected (on the basis of cost) to forgo a recommended MRI, Dr. Severyn said he would dismiss the patient "[i]f I felt strongly enough about it." 70 Elaborating, he said that if a patient was presenting signs and symptoms "of a worsening nerve injury" and if he felt the patient's health "would be permanently impaired because of a nerve injury and if the patient continued to insist that they were not going to or be able to obtain an MRI, I would seriously consider withdrawing care from that [patient]."71

Another resource available to physicians in Ohio, according to Dr. Severyn, is the Ohio Automated Rx Reporting System, or OARRS.72 Asked during cross examination whether consulting this reporting system constitutes an attempt by a physician to address a red flag, Dr. Severyn said yes, "OARRS reports are tremendously helpful and the requirement to check them, as a standard of care, is valid." 73 Dr. Severyn was asked if he knew Dr. Zaidi conducted such a check on each patient.74 Dr. Severyn indicated that he was not aware that this was a part of Dr. Zaidi's prescription practice.<sup>75</sup> There is, however, some evidence from Ms. Maniglia that she would print out an OARRS report for every new patient.76

Dr. Severyn also was asked whether transitioning from an immediate-release form of Oxycodone to a time-released form is another means of responding to

red flags. 77 After noting that time-released OxyContin "can be converted to immediate release Oxycodone by crushing or chewing or otherwise altering it," Dr. Severyn stated that while there is some protection against abuse, "the choice of a time release medication is less driven by red flags and the issue of abuse than it is driven by the intent to follow a medical treatment plan that provides a more steady state of medication." 78 He said time-release OxyContin is "less likely, to a degree, to lead to diversion or to lead to addiction, but...[i]t's only to

a degree that makes it a little more

abusing the medication or seeks to

divert the medication, to do so

successfully." <sup>79</sup>
Two of the undercover agents represented to Dr. Zaidi they suffered from pain or stiffness in the lower back. <sup>80</sup> When asked what he does when a patient presents with a complaint of back pain, Dr. Severyn gave this

difficult for the patient who seeks to be

response:

I want to find out some basic information about the patient. Where is your pain? Does it radiate into the legs? For how long have you had it? What makes it better? What makes it worse? Have any procedures or surgeries been done to make a difference in this, in the past, and zero to ten, what is your severity of pain? Have you had physical therapy? Has that been helpful for you in the past? Might it be something to consider again? Then I look at the OARRS report, because I want to know how accurate is my patient's reported history in comparison to what has already been documented as being dispensed. Next, I look through the medical record to see if at Ohio State, during any of the time that the patient has been seen, there is a urine drug screen present. If so, I copy it into the medical record and make a decision, then and there, if I'm going to be obtaining another one.81

Dr. Severyn explained that because his practice at The Ohio State University is a referral practice, the patients he sees usually are being cared for by other members of OSU's medical staff. Because He said if he is prescribing controlled substances he will order a urine drug screen, and "go through all of the areas of the portion of the administrative rule that pertains to the initial prescribing" of controlled substances. After that, he will review "the past medical history, which, of course, is medical history, surgical history, medication history, [and] social

<sup>&</sup>lt;sup>58</sup> *Id.* at 66.

 $<sup>^{59}\,\</sup>text{Id.}$  at 223. OARRS is the Ohio Automated Rx Reporting System. Tr. at 471, 602.

<sup>&</sup>lt;sup>60</sup> Tr. at 233.

<sup>61</sup> Id. at 67.

<sup>62</sup> *Id* 

<sup>63</sup> Id. at 68.

<sup>64</sup> *Id.* at 173.

<sup>65</sup> Id. at 224-25.

<sup>66</sup> Id. at 172.

<sup>&</sup>lt;sup>67</sup> Id.

<sup>68</sup> Id. at 182.

<sup>69</sup> Id. at 184-85.

<sup>&</sup>lt;sup>70</sup> *Id.* at 185.

<sup>&</sup>lt;sup>71</sup> *Id*.

<sup>72</sup> Id. at 178.

<sup>&</sup>lt;sup>73</sup> Id.

<sup>&</sup>lt;sup>74</sup> Id. <sup>75</sup> Id

<sup>&</sup>lt;sup>76</sup> *Id.* at 414.

<sup>&</sup>lt;sup>77</sup> *Id.* at 180.

<sup>&</sup>lt;sup>78</sup> Id.

<sup>79</sup> Id. at 213-14.

<sup>80</sup> Gov't Ex. Nine at 3; Gov't Ex. Ten at 6.

<sup>81</sup> Tr. at 216-17.

<sup>&</sup>lt;sup>82</sup> Tr. at 220.

<sup>&</sup>lt;sup>83</sup> Id.

history. After that, it's going to be a review of symptoms, which is about 50 specific symptoms to do, and then I'm going to go through my physical examination." 84 He would then check for imaging, if any is available, and following that he would make his assessment and diagnosis, which he will discuss with the patient.85 From there, the patient must decide the course of action based on Dr. Severyn's recommended course of action, after which prescriptions can be written along with any other orders, and arrangements are made for follow up visits.86

#### Dr. Zaidi's Treatment of Officer Tyler Parkison (Under the Name Tyler Williams)

Tyler Parkison is a DEA Special Agent, a position he has held since 2008.87 Between 2005 and 2008 he was a DEA Diversion Investigator, having graduated from the DEA's twelve-week training academy at Quantico, Virginia.88 As a diversion investigator, Agent Parkison was trained in the investigation of criminal and regulatory cases, including those involving drug audits and identification and the execution of warrants.89 Agent Parkison has been trained in the use of firearms, undercover operations, surveillance, physical fitness, financial investigations, and drug identification.90

Agent Parkison stated that the investigation into Dr. Zaidi's prescription practice began after an agent in his office received a complaint indicating "suspicious prescribing involving controlled substances" along with a complaint alleging a family member of the complainant "was addicted to Dilaudid" and an allegation that "there were drug transactions taking place in the parking lot" of Dr. Zaidi's practice.<sup>91</sup> Included in the report by the complainant was the assertion that "patients were going in and out very quickly, that they were seeing up to ten to fifteen people in an hour." Acting on this information, Agent Parkison obtained a report from OARRS setting forth the prescription history for Dr. Zaidi, revealing that "the amounts of Schedule II drugs that he was prescribing was very high." 93 When

<sup>84</sup> *Id*.

asked to elaborate on this during cross examination, Agent Parkison said that based on his experience, Dr. Zaidi's prescriptions for Schedule II drugs seemed high when compared with "a couple" of other physicians he had been investigating. 94 Given this information, Agent Parkison "decided to schedule an office visit at Pain Management of Northern Ohio." 95

In his investigation of Dr. Zaidi, Agent Parkison acted in an undercover capacity under the name Tyler Williams, <sup>96</sup> and also was part of the team that executed a search warrant and retrieved records from Dr. Zaidi's office. <sup>97</sup> He acknowledged, during cross examination, that he approached Dr. Zaidi as an undercover agent intending to falsely report that he had pain, but he denied attempting to fool Dr. Zaidi. <sup>98</sup>

Agent Parkison's first of five visits to Dr. Zaidi's office was recorded in audio and audio/video recordings, the transcripts of which are in our record.99 Agent Parkison explained that the first visit took place on September 11, 2012, and confirmed that Government Exhibit 3a contains a video recording of that visit.100 I viewed this video, and found that Dr. Zaidi's medical office appears to be furnished and staffed in a manner similar to many office practices: The office is located in an office complex, and upon passing through a hallway, Agent Parkison opened the door to find a reception area in which a receptionist took his name and driver's license, while a billing clerk (later identified as Kim Maniglia) spoke on the telephone regarding authorization for an imaging procedure and another staff member in clinical garb entered and left the receptionist's office. 101

Ms. Maniglia explained that she has been employed at Pain Management of Northern Ohio for twelve and a half years. <sup>102</sup> She said Dr. Zaidi owns the business, and that she does all of the billing for the business, and also works at the front desk. <sup>103</sup> She explained that while she has no medical training and does not participate in patient treatment, she does have a role in filling out prescriptions for the office. <sup>104</sup> She stated that for every new patient, Dr. Zaidi runs an OARRS report—she prints

out the report and puts them in the new patient's file for Dr. Zaidi to review. 105 The reports indicate what prescriptions the patient is getting and what doctors the patient has seen. 106 According to Ms. Maniglia, after Dr. Zaidi sees a patient, the patient's medical chart comes to her, at which point she reads what Dr. Zaidi has written and logs prescription information into the back of the chart. 107 After the patient is seen, she shreds the OARRS report. 108

According to Ms. Maniglia, Dr. Zaidi requires urine drug screening for all new patients, and uses such screens periodically throughout the patient's treatment. 109 She added that if a patient does not "have good urine Dr. Zaidi usually writes on the bottom not to fill any scripts for them" or may indicate "NPUS" on the chart, to direct "no prescriptions until seen." 110 Based on what Dr. Zaidi has written, Ms. Maniglia will write the prescription information on a blank prescription form. 111 She said that Dr. Zaidi would sign blank prescriptions in the morning, and after they were signed she would fill out the prescriptions throughout the day, using the signed forms. 112

Ms. Maniglia explained that there may be days when prescriptions that Dr. Zaidi has signed are not actually needed that day, so "[t]here might have been a few left over," but when that happens the signed prescriptions are stored "triple-locked up in the drug cart" and are used the next day. 113 Ms. Maniglia acknowledged that some of these prescriptions have been for controlled substances.<sup>114</sup> She said Dr. Zaidi trained her in this aspect of her job, and she has performed these tasks for more than twelve years. 115 When asked whether Dr. Zaidi ever mentioned the need to have a patient's address on the prescription, Ms. Maniglia said no, even with prescriptions for controlled substances, "we just need two identities, just the birth date and the name." 116

Affixed to the window separating the waiting area from the receptionists office are stickers indicating payment could be made using Visa, Diners Club, MasterCard and Discover, along with a sign that states the staff is not permitted

<sup>&</sup>lt;sup>85</sup> *Id.* at 221.

<sup>86</sup> Id.

<sup>87</sup> Id. at 296.

<sup>88</sup> Id.

<sup>89</sup> Id. at 297.

<sup>90</sup> Id. at 299.

<sup>91</sup> *Id.* at 320.

<sup>93</sup> Id. at 320-21.

<sup>94</sup> Id. at 436.

<sup>95</sup> *Id.* at 321.

<sup>96</sup> *Id.* at 309. 97 *Id.* at 299.

<sup>98</sup> *Id.* at 445.

<sup>99</sup> Gov't Exs. 3a through 3e; Gov't Ex. Nine.

<sup>&</sup>lt;sup>100</sup> Tr. at 300–01.

<sup>&</sup>lt;sup>101</sup>Gov't Ex. 3a, folder AudioVideo Recordings—09–11–12, file 105605 at 10:57:05–10:59:43.

<sup>102</sup> Tr. at 406.

<sup>&</sup>lt;sup>103</sup> *Id*.

<sup>104</sup> Id. at 407.

<sup>&</sup>lt;sup>105</sup> *Id.* at 414.

<sup>&</sup>lt;sup>106</sup> Id. at 415.

<sup>&</sup>lt;sup>107</sup> *Id.* at 407.

<sup>&</sup>lt;sup>108</sup> *Id*.

<sup>&</sup>lt;sup>109</sup> Id.

<sup>111</sup> Id.

<sup>&</sup>lt;sup>111</sup> *Id.* <sup>112</sup> *Id.* 

<sup>113</sup> Id. at 408-09.

<sup>&</sup>lt;sup>114</sup> *Id.* at 410.

<sup>&</sup>lt;sup>115</sup> *Id.* at 428–29. <sup>116</sup> *Id.* at 429.

to accept any homemade food, and another that states co-payments are to be paid at the time of the office visit. 117 The waiting area is appropriate in size, judging from the eight to ten office chairs that were visible in the video, and was sufficient for the three or four patients waiting in the room.118

The receptionist area appeared to be equipped with telephones, computers, fax, copy, or multifunction machines, and file cabinets that typically are found in offices of this size. 119 The overall impression was that this was a fully functional small medical practice. According to Agent Parkison, Dr. Zaidi was the only doctor at the office of Pain Management of Northern Ohio. 120 There was no evidence that the office accepted only cash, or that it refused to treat persons covered by insurance. In fact, Ms. Maniglia can be heard on the phone confirming approval for a "three-level lumbar discogram," which suggests she was confirming this service would be paid for by the patient's health insurance. 121 During the hearing, Ms. Maniglia explained that on average, the office will deposit about \$3,000 per week in cash, but that most of the office gross receipts, roughly 80 percent, come from insurance providers. 122

Ms. Maniglia was asked to recall what she was asked when DEA agents came to Dr. Zaidi's office to search the premises.123 She said the agent, whom she referred to only as Damien, asked about Dr. Zaidi's children, the car he drives, and his religion.124 She said they also asked if Dr. Zaidi kept controlled substances in the office, and she responded that he does not, not even samples.125

Ms. Maniglia also testified about what she told DEA investigators with respect to doctor shopping. She said she understood doctor shopping involved patients going to different doctors in order to get multiple prescriptions for controlled substances. 126 She was asked whether she was aware of any instances where Dr. Zaidi's patients may have been accused of doctor shopping, and responded that she has "nothing to do with the patients" when they are in the back being examined by Dr. Zaidi. 127

She did, however, recall being asked by law enforcement officers during the search of Dr. Zaidi's office, about patients who might be involved in doctor shopping. 128 She said the officer who claims she told him she was not allowed to report such patients to law enforcement misunderstood her—that under HIPAA "we weren't allowed to discuss anything" regarding such patients. 129 Apparently Ms. Maniglia understood that under HIPAA, staff members were not permitted to contact law enforcement due to "patient confidentiality," but she added that her understanding was not the result of instructions from Dr. Zaidi. 130 Rather, her understanding of this restriction was based on her work "in the field for 20 years and we're not allowed to talk about any patient confidentiality stuff." 131 She denied, however, being instructed not to call authorities if there were dirty urine screens or if an OARRS report showed multiple doctor encounters, adding, "We've never talked about it." 132

At the time search warrants were being executed, DEA Diversion Investigator Scott Brinks questioned Dr. Zaidi regarding his office practice. 133 Investigator Brinks said Dr. Zaidi consented to the interview, and when asked about pre-signed prescriptions found in the office, responded by telling Investigator Brinks that he did pre-sign them, and agreed that they were presently blank but for the signature. 134 Investigator Brinks also stated Dr. Zaidi confirmed writing a prescription for Vicodin to his daughter. 135 He added, however, that he did not know whether the prescription was for emergency treatment, nor whether the prescription was ever filled. 136

In addition to providing insight into the operations of Dr. Zaidi's medical office at the time of the execution of the DEA's search warrant, the Government also included in the record transcripts and recording showing how Dr. Zaidi's office staff handled patient visits. Generally, a staff assistant would conduct an initial intake interview with the patient, and then Dr. Zaidi would review the intake forms and meet with the patient. 137 At subsequent office visits, the staff member would continue to conduct an initial review of current symptoms with the patient, and thereafter Dr. Zaidi would briefly meet with the patient and determine whether to continue to prescribe controlled substances. 138

Christy Barrett, a member of Dr. Zaidi's office staff, conducted an intake interview with Agent Parkison, lasting approximately nine minutes. 139 During this interview, Ms. Barrett took Agent Parkison's blood pressure; pulse; and pulse oxygen levels; asked his height and weight; inquired about his level of pain and location of pain; use of tobacco, alcohol, and caffeine; past surgeries and physical therapy; past MRIs; use of blood thinners; and could be seen filling out the medical intake form. 140 She then went through the contents of a pain management contract, which Agent Parkison had signed prior to this interview.<sup>141</sup> At the end of the intake interview, she directed Agent Parkison to provide a urine sample for a drug screen. 142

The doctor's examination took place in a room that appeared to be wellequipped with modern, functional furnishings, including a full-size examination table. 143 Dr. Zaidi greeted Agent Parkison as "Mr. Tyler," reviewed papers contained in a folder, and asked questions regarding his medical history for approximately one minute.144 Although Agent Parkison told Dr. Zaidi he did concrete work, there was never any discussion about whether the work involved heavy lifting or any other physical activity.<sup>145</sup> Also, although Agent Parkison wrote in his history that he had a work-related injury, during the interview with Dr. Zaidi he denied being injured; yet, according to Agent Parkison, this inconsistency was never addressed by Dr. Zaidi. 146

Dr. Zaidi discussed Agent Parkison's hypertension, and then had Agent Parkison stand, bend from the waist forward then back, walk on his toes and heels, and thereafter told Agent Parkison he had slight scoliosis, ending the examination after approximately 60

<sup>117</sup> Gov't Ex. 3a, folder AudioVideo Recordings-09-11-12, file 105605 at 10:59:08-09.

<sup>118</sup> Id. at 11:00:37-11:01:27.

<sup>119</sup> Id. at 10:57:44-10:57:46.

<sup>120</sup> Tr. at 339.

<sup>121</sup> Gov't Ex. 3a, folder AudioVideo Recordings-09-11-12, file 105605 at 10:57:51-10:58:13.

<sup>&</sup>lt;sup>122</sup> Tr. at 426.

<sup>123</sup> Id. at 420-21.

<sup>124</sup> *Id.* at 421.

<sup>125</sup> Id

<sup>126</sup> *Id.* at 410.

<sup>127</sup> Id.

<sup>128</sup> Id. at 411.

<sup>129</sup> Id.

<sup>130</sup> Id. at 412.

<sup>131</sup> *Id*.

<sup>132</sup> Id. at 416.

<sup>133</sup> Id. at 618.

<sup>134</sup> Id. at 618-19.

<sup>135</sup> *Id.* at 619.

<sup>136</sup> Id. at 620.

<sup>137</sup> See, e.g., Gov't Ex. 3a folder AudioVideo Recordings 09-11-12, file 114021.

<sup>138</sup> See, e.g., Gov't Ex. 3a, folder AudioVideo Recordings 09-11-12, file 115238.

<sup>&</sup>lt;sup>139</sup>Gov't Ex. 3a, folder AudioVideo Recordings 09-11-12, file 114021.

<sup>&</sup>lt;sup>140</sup> Id. at 11:40 to 11:47; Gov't Ex. Twelve at 19. 141 Gov't Ex. 3a, folder AudioVideo Recordings 09-11-12, file 114021 at 11:47 to 11:49; Gov't Ex.

<sup>142</sup> Gov't Ex. 3a, folder AudioVideo Recordings 09-11-12, file 114021 at 11:49 to 11:51.

<sup>143</sup> Gov't Ex. 3a, folder AudioVideo Recordings 09-11-12, file 115238.

<sup>144</sup> Id. at 11:54 to 11:55.

<sup>&</sup>lt;sup>145</sup> Tr. at 331.

<sup>146</sup> Id.

seconds.<sup>147</sup> After confirming he had no medical insurance, Dr. Zaidi told Agent Parkison that he would order an MRI, but it would be acceptable if Agent Parkison elected to wait for two weeks before getting the imaging, and added that there was a source for MRIs that would provide the service for \$350 to uninsured patients of the office, if that was what Agent Parkison decided to do.<sup>148</sup>

Without discussing the possibility of physical therapy or home exercises, 149 Dr. Zaidi wrote a prescription for 20 tablets of Percocet five mg, 150 charged a \$300 fee for the office visit, 151 and directed that Agent Parkison return in two weeks. 152 Dr. Zaidi added that they could discuss whether epidural injections might help, asked additional questions regarding Agent Parkison's medical history and ended the visit (although at this time Dr. Zaidi took no further notes while on camera). 153 154

After confirming that he reviewed the undercover recordings and the entire medical record maintained by Dr. Zaidi regarding treatment of Agent Parkison (under the name Tyler Williams), Dr. Severyn expressed opinions regarding both Dr. Zaidi's physical examination of Agent Parkison and the medical history that supported Dr. Zaidi's decision to prescribe controlled substances to this patient.<sup>155</sup> As noted above, prior to meeting with Dr. Zaidi, Agent Parkison met with and was interviewed by Christy Barrett. 156 Dr. Severyn opined that when Ms. Barrett took Agent Parkison's blood pressure and pulse oximetry readings, inquired of his medical history, and inquired of his pain level and functional capacities,157 "that encounter and the collection of information satisfies the requirement of a minimum standard of care" for taking the history of a patient, but not "for initially prescribing a controlled substance to a patient who will

ultimately be receiving it for longer than twelve weeks."  $^{158}$ 

Dr. Severyn noted that the patient "is acknowledging no past medical history, no past surgical history, and having been completely healthy all of his life" until two weeks prior to the visit, when he experienced lower back pain. 159 Rating his pain at a four (on a ten-point scale), the patient did not acknowledge having any pain radiating to his legs, nor any weakness or numbness; and indicated he was employed as a concrete worker at a construction company at the time of the office visit. 160

When Dr. Severyn compared what was in the written medical chart 161 with what he observed while watching the audio/video recording of the initial office visit, he noted the following. First, he noted that the written medical chart indicates that the patient's pupils were equal when reacting to light, and explained that to make this determination, "[the] physician needs to shine a light into one pupil and then into the other pupil. And I didn't find any evidence in the video recording or in the transcript that that was occurring" during this office visit. 162 Similarly, he found the written entry indicating that the oral mucosa (i.e., the inside of the mouth) was moist and pink, but saw no evidence that the patient was ever asked to open his mouth while Dr. Zaidi examined its interior. 163

Next, Dr. Severyn noted that a cranial nerve examination was indicated in the written notes. <sup>164</sup> He explained that an examination of the cranial nerve is conducted by touching the neck to determine the size of the thyroid gland, and by touching the armpits to determine whether the axillary lymph nodes were enlarged—neither of which were performed during this examination. <sup>165</sup> Also included in such an examination is a range of motion test for the neck, which Dr. Severyn said he did not find in the recording or the transcript. <sup>166</sup>

Similarly, although the medical record indicates normal sensory and motor testing, "[t]here was no testing that went on with sensation of the arms, the hands, or the range of motion or strength of the fingers, the wrists, the

biceps, and triceps." <sup>167</sup> Further, there is an entry indicating normal range of motion in all the joints of the upper extremities, but such an examination did not occur, according to Dr. Severyn. <sup>168</sup>

Dr. Severyn noted that Dr. Zaidi reported mild scoliosis without deformity, but also that the lower extremities were normal with respect to sensation and strength, and that the "[a]bdomen is soft and nontender." 169 Dr. Severyn said that Dr. Zaidi certainly would have seen the patient walk as part of the office visit, and would thereby be able to report that the patient's balance and coordination were normal, and confirmed that Dr. Zaidi had the patient perform heel and toe walking (which were described as normal).<sup>170</sup> He did not, however, see Dr. Zaidi touch the patient's abdomen to test it for softness and for the presence of tenderness.171

Next, Dr. Severyn said that while the medical records indicate a chest examination was performed, "to do that requires the use of a stethoscope, and a stethoscope was nothing that I could observe during any of the recording of this encounter." <sup>172</sup> He said the same was true regarding the notation of normal heart sounds—heart sound examinations require a stethoscope, but none was observed during the video recording of this examination. <sup>173</sup>

Dr. Severyn opined that the report of this patient's examination was falsified in that "it is embellished, and it is inaccurate, to the point that much of it, though documented here, was not performed." <sup>174</sup> Moreover, in his opinion, the medical history described a patient with "an acute condition of mild severity and of a generally benign nature" that would not "justify prescribing a controlled substance or relying upon a controlled substance as the predominant approach to treatment." <sup>175</sup>

Also of concern, according to Dr. Severyn, was Dr. Zaidi's diagnosis indicating thoracic and lumbar radiculitis. Dr. Severyn stated:

Radiculitis is a diagnosis of nerve root dysfunction at the level of the spine, at the level where the nerve roots exit the spine. If it is lumbar radiculitis, then it is a nerve root that's exiting in the lumbar area, and so for the thoracic area, radiculitis is a condition

 $<sup>^{147}\,\</sup>rm{Gov't}$  Ex. 3a, folder Audio Video Recordings 09–11–12, file 115238 at 11:55:17 to 11:56:15.

<sup>148</sup> Id. at 11:56:16 to 11:57:300.

<sup>149</sup> Tr. at 333.

 $<sup>^{150}\,\</sup>mathrm{Percocet}$  is the brand name of a combination of Oxycodone and Acetaminophen. Tr. at 254.

<sup>&</sup>lt;sup>151</sup> Tr. at 309.

<sup>&</sup>lt;sup>152</sup>Gov't Ex. Nine at 8.

<sup>&</sup>lt;sup>153</sup> Gov't Ex. 3a, folder AudioVideo Recordings 09–11–12, file 115238 at 11:56:38 to 11:58:16.

<sup>&</sup>lt;sup>154</sup>Gov't Ex. 3a also included files 111619, 112129, and 112930. After I watched and listened to each of these, I found no information relevant to this proceeding in these files. The exhibit also includes an audio-only file identified as CCR\_0001, which neither party referred to during the hearing and which did not appear to have any information relevant to this proceeding.

<sup>&</sup>lt;sup>155</sup> Tr. at 69–70.

<sup>156</sup> Gov't Ex. Nine at 1-6.

<sup>157</sup> *Id*.

 $<sup>^{158}\,\</sup>mathrm{Tr.}$  at 237–39.

<sup>159</sup> Id. at 70-71.

 $<sup>^{160}</sup>$  Id. at 71; Gov't Ex. Twelve at 19.

<sup>161</sup> Gov't Ex. Twelve at 7.

<sup>162</sup> Gov't Ex. Twelve at 7; Tr. at 72.

<sup>&</sup>lt;sup>163</sup>Gov't Ex. Twelve at 7; Tr. at 72–73.

 $<sup>^{164}</sup>$  Gov't Ex. Twelve at 7; Tr. at 73.

 $<sup>^{165}\,</sup>Gov't$  Ex. Twelve at 7; Tr. at 73.

<sup>&</sup>lt;sup>166</sup> Tr. at 73.

 $<sup>^{167}\,</sup>Gov't$  Ex. Twelve at 7; Tr. at 73–74.

 $<sup>^{168}\,</sup>Gov't$  Ex. Twelve at 7; Tr. at 74.

<sup>&</sup>lt;sup>169</sup>Gov't Ex. Twelve at 7; Tr. at 74.

<sup>170</sup> Gov't Ex. Twelve at 7; Tr. at 75.

<sup>&</sup>lt;sup>171</sup> Gov't Ex. Twelve at 7, 11. at 75.

<sup>&</sup>lt;sup>172</sup>Gov't Ex. Twelve at 7, 11. at 75.

<sup>&</sup>lt;sup>173</sup> Gov't Ex. Twelve at 7; Tr. at 75.

<sup>&</sup>lt;sup>174</sup> *Id.* at 76.

<sup>175</sup> Id.

that will then affect the entire nerve root to some degree or another, but it is not pain that is limited to just the portion of the back. We call that instead axial pain. It has other causes. That is the use of the word lumbago, which is lumbar pain.

But, putting a diagnosis of radiculitis as opposed to other causes, that, based on this history and the lumbar portion of the examination are much more reasonable, brings to my mind the question as to the accuracy of that diagnosis, because I think that an experienced physician, especially one in the field of pain medicine, would recognize that this is not the presentation and the examination that's compatible with a diagnosis of radiculitis. This diagnosis is blatantly inaccurate. 176

Accordingly, Dr. Severyn opined that both the treatment plan and the recommendation for this patient were "not justified by the presentation of this patient." <sup>177</sup>

Dr. Severyn expressed the same opinion regarding Dr. Zaidi's diagnosis of lumbar radiculitis during the followup visit on October 4, 2012, based on what he observed from the recordings of the follow-up visit and what appears in Dr. Zaidi's written notes of that encounter.178 He said Dr. Zaidi's notation that he conducted a physical examination during that visit allowing him to find moderate tenderness and spasm in the paralumbar muscles (with guarding and forward flexing) was falsified, as was his description of a lower extremity examination establishing normal sensory and motor testing.179

The October 4, 2012 visit began with Ms. Barrett <sup>180</sup> taking Agent Parkison's blood pressure and pulse oximetry, <sup>181</sup> and recording her findings while seated and using the examination table as her desk. <sup>182</sup> Ms. Barrett inquired of Agent Parkison's current pain level, which he stated was three or four, with the best level around two and worst pain at four. <sup>183</sup> Those pain levels are recorded in notes apparently written by Ms. Barrett, indicating current pain as a four, with worst pain at four and best pain at two. <sup>184</sup> At no time did Agent Parkison indicate a pain level as high as five.

As Ms. Barrett finished her notes in the file, Dr. Zaidi entered and Ms. Barrett stood up from behind the

examination table, at which point Dr. Zaidi took the seat and briefly turned his back to Agent Parkison and consulted his computer monitor. $^{185}$  Dr. Zaidi then turned to face Agent Parkison, and began his interview, asking about whether the Percocet had been effective and discussing his concerns about Agent Parkison's blood pressure, which he said was high and created the risk of stroke. 186 When Dr. Zaidi asked how the Percocet was working, Agent Parkison stated "it worked pretty good, it worked alright; I just felt like I didn't quite have enough of it." 187 They did not, however, discuss whether Agent Parkison had taken all of the prescribed Percocet. 188

Agent Parkison then asked Dr. Zaidi "if I could get a little bit more" and hoped "to try two in the morning and two in the evening." <sup>189</sup> Without more, Dr. Zaidi stated "Okay. So I'll give you four a day." <sup>190</sup> Based on this examination, Dr. Zaidi gave Agent Parkison a prescription for 56 Percocet five mg tablets. <sup>191</sup>

In his transcribed notes for the subjective examination, Dr. Zaidi wrote:

[Agent Parkison] is stable with his lower back pain at 5 on a scale of 0–10. No change in his personal, family, or social history. No focal weakness or numbness. No abdominal or chest pain. His blood pressure is again very elevated. We again discuss the potential complications from such high blood pressure and he is to go and see his PCP today or ER to have that addressed. Otherwise, no abdominal or chest pain at present. No headaches. No visual disturbances. 192

In his report of objective findings, Dr. Zaidi wrote that Agent Parkison's "vital signs are stable though blood pressure is elevated. Moderate tenderness and spasm in paralumbar muscles with guarding in forward flexion. Lower extremity examination is normal to sensory and motor testing. His gait is normal." <sup>193</sup> Having seen the audiovideo recording of this encounter, I find no evidence that Dr. Zaidi has accurately described the scope of his physical examination, and consistent with Dr. Severyn's findings, I find this to be a falsified examination report.

By this point in the visit, Dr. Zaidi had spent approximately two minutes in the room with Agent Parkison, all of it seated, with the examination table between himself and Agent Parkison. 194 As Dr. Severyn noted, there is no evidence that Dr. Zaidi performed any physical examination either before or after agreeing to increase the Percocet prescription. 195 Indeed, the discussion predominating this visit addressed Agent Parkison's high blood pressure, not his pain or his treatment for pain. There was no discussion about exercise, physical therapy, injections, alternatives to the use of controlled substances, or Agent Parkison's functional capacity.

Dr. Severyn remarked that there was a notation regarding home exercise as part of the plan of treatment.196 He added, however, that he found nothing in the material that "contained any educational endeavor that would allow someone to conduct a home exercise program."  $^{\rm 197}$  He explained that in order to provide a home exercise program to a patient, "there would need to be either verbal or oral communication. It would include instructions as to what are the physical maneuvers to be performed, the frequency, the timing, and the expected response and instructions as to how to avoid exacerbating the condition." 198 While this could be accomplished by handing the patient various brochures that might explain a home exercise program for this kind of pain, there is nothing in the record to indicate such education took place. 199 Agent Parkison confirmed this, testifying that at no time during any of his office visits did Dr. Zaidi provide him with examples of exercises he could perform to treat his back pain, nor was there any discussion about a home exercise program.<sup>200</sup>

Despite the paucity of information gathered during this second visit, Dr. Zaidi increased by one hundred percent the number of Percocet tablets he prescribed to Agent Parkison.<sup>201</sup> According to Dr. Severyn, there was no justification presented in the medical record for doubling the amount of Percocet to Agent Parkison.<sup>202</sup> Dr. Severyn explained that while Agent Parkison's continued complaint of pain should be considered, Dr. Zaidi should have considered alternatives to

<sup>&</sup>lt;sup>176</sup> *Id.* at 77–78.

<sup>&</sup>lt;sup>177</sup> *Id.* at 79.

<sup>&</sup>lt;sup>178</sup> *Id.* at 80.

<sup>&</sup>lt;sup>179</sup>Gov't Ex. Twelve at 12; Tr. at 81.

<sup>180</sup> Gov't Ex. Nine at 11.

<sup>&</sup>lt;sup>181</sup> Tr. at 232.

 $<sup>^{182}</sup>$  Gov't Ex. 3b, folder Tyler UC visit, subfolder AudioVideo Recordings—10–04–12, file 102359 at 10:24:38 to 10:26:40.

<sup>&</sup>lt;sup>183</sup> *Id.:* Gov't Ex. Nine at 11.

<sup>184</sup> Gov't Ex. Twelve at 18.

<sup>&</sup>lt;sup>185</sup> Gov't Ex. 3b, folder Tyler UC visit, subfolder AudioVideo Recordings—10–04–12, file 102359 at 10:26:31–10:27:05.

<sup>&</sup>lt;sup>186</sup> Gov't Ex. 3b, folder Tyler UC visit, subfolder AudioVideo Recordings—10–04 12, file 102359 at 10:27:05 to 10:28:11.

<sup>&</sup>lt;sup>187</sup> *Id.;* Gov't. Ex. Nine at 13.

<sup>188</sup> Tr. at 336.

 $<sup>^{\</sup>rm 189}\, Gov\ensuremath{^{\circ}} t$  Ex. Nine at 13.

<sup>190</sup> Id.

<sup>&</sup>lt;sup>191</sup> Tr. at 310; Gov't Ex. Fifteen at 2.

<sup>&</sup>lt;sup>192</sup> Gov't Ex. Twelve at 12.

<sup>&</sup>lt;sup>193</sup> *Id*.

<sup>&</sup>lt;sup>194</sup>Gov't Ex. 3b, folder Tyler UC visit, subfolder AudioVideo Recordings—10–04 12, file 102359 at 10:26:31 to 10:28:40.

 $<sup>^{195}\,{</sup>m Tr.}$  at 80.

<sup>&</sup>lt;sup>196</sup> *Id.* at 81.

<sup>&</sup>lt;sup>197</sup> Id.

<sup>198</sup> Id. at 84-85.

<sup>&</sup>lt;sup>199</sup> *Id.* at 85.

<sup>&</sup>lt;sup>200</sup> Id. at 350.

<sup>&</sup>lt;sup>201</sup> *Id.* at 85.

<sup>&</sup>lt;sup>202</sup> Id.

controlled substances as treatment.<sup>203</sup> Dr. Severyn opined that when Dr. Zaidi prescribed 56 Percocet tablets for Agent Parkison during this visit, he did so outside the usual course of professional practice.<sup>204</sup>

According to Dr. Severyn, Agent Parkison's next visit, on November 14, 2012, did not include an examination of the lumbar spine, nor any testing for guarding in forward flexion, nor was there any sensory or motor testing of the lower extremities.<sup>205</sup>

Having reviewed the audio-video recording of the November 14, 2012 office visit, I concur with Dr. Severyn's assessment and find there was no examination of Agent Parkison's lumbar spine during this visit, nor was there any testing for guarding in forward flexion, nor was there any sensory or motor testing of the lower extremities.<sup>206</sup>

Agent Parkison stated that for this visit, he reported a current pain level of two and the worst level had been a three.207 In taking his history for this visit, Ms. Barrett accurately recorded in his patient medical chart that Agent Parkison reported a maximum pain level of three, a minimum of two, and a present level of two.208 After Ms. Barrett obtained Agent Parkison's blood pressure and oximetry readings and recorded his responses to her questions about current and recent pain levels, Ms. Barrett left the room and Dr. Zaidi entered shortly thereafter.<sup>209</sup> Dr. Zaidi remained standing near the office door and reviewed the chart provided to him by Ms. Barrett, and for approximately two minutes discussed with Agent Parkison his high blood pressure and the steps he should be taking to address that problem.<sup>210</sup> At no time did Dr. Zaidi place his hands on Agent Parkison or approach him—instead, he stood by the chart until he determined that the pain medication was working and completed his discussion regarding the seriousness of Agent Parkison's elevated blood pressure.211

Based on this encounter, Dr. Zaidi made written subjective findings, stating that Agent Parkison's "lumbar pain is at 5 on a scale of 0-10" despite the notations to the contrary in the chart prepared by Ms. Barrett and despite the absence of any evidence indicating Agent Parkison was reporting pain at that level.<sup>212</sup> Despite the lack of questions (by either Ms. Barrett or Dr. Zaidi) addressing these subjects, Dr. Zaidi wrote there was "[n]o change in his personal, family, or social history." 213 Despite the absence of any physical examination or questions presented to Agent Parkison regarding these areas, Dr. Zaidi wrote in his subjective findings that there were no abdominal or chest pains, and no focal weakness or numbness.214

Consistent with what Agent Parkison told Dr. Zaidi, in the Objective findings section Dr. Zaidi noted Agent Parkison's continued high blood pressure, adding, "He has seen his PCP and has been asked to monitor it at home, and I asked him to make a follow-up again very soon." 215 Dr. Zaidi accurately reported that they again discussed the potential complications of hypertension.<sup>216</sup> He continued, however, to report "[m]oderate tenderness and spasm in paralumbar muscles with guarding in forward flexion. Lower extremity examination is normal to sensory and motor testing." 217 Also, despite the fact that Agent Parkison was seated throughout his encounter with Dr. Zaidi during this visit, Dr. Zaidi wrote that Agent Parkison's "gait is normal." <sup>218</sup> Based on these subjective and objective findings, Dr. Zaidi wrote that the impression is that of lumbar radiculitis, and issued a prescription for 56 tablets of Percocet five mg.<sup>219</sup>

Dr. Severyn opined that Dr. Zaidi's diagnosis of lumbar radiculitis "is a more severe condition than what this patient is voicing complaints [] of," and "is not justified on the basis of the entirety of the history and the physical examination." <sup>220</sup> He explained that the objective findings that appear in Dr. Zaidi's written report of the November 14, 2012 visit—including spasms in paralumbar muscles and guarding in forward flexion—could not be reached without a physical examination, but that there was no evidence that such an

examination occurred.<sup>221</sup> I too saw no evidence of an examination during this visit.

Dr. Severyn also noted that while the written record of treatment for November 14, 2012, reports Agent Parkison reported pain at level five (on a scale of ten), the recording and transcript show that Agent Parkison reported pain at level two to three—and there is no explanation to account for this difference.<sup>222</sup>

The Government also presented testimony from DEA Diversion
Investigator Brinks, who was present when Agent Parkison interviewed Dr. Zaidi at the time the DEA's search warrant was executed. <sup>223</sup> Investigator Brinks testified that Agent Parkison had the medical chart reflecting pain levels higher than Agent Parkison reported to either Dr. Zaidi or Ms. Barrett, and asked Dr. Zaidi if he could explain this difference. <sup>224</sup> According to Investigator Brinks, Dr. Zaidi had no response when presented with Agent Parkison's treatment chart. <sup>225</sup>

Dr. Severyn was asked to interpret the exchange between Dr. Zaidi and Agent Parkison, where the latter, during his visit of December 12, 2012, told Dr. Zaidi that his current medication has "been helping some at the end of the day," but that he had "a little bit of nagging stiffness," adding that one of his "buddies said something that [OxyContin] kind of helps him." <sup>226</sup> Without more, according to Dr. Severyn, this would not be a sufficient justification for changing a medication to OxyContin, but that is what Dr. Zaidi did.<sup>227</sup>

The audio-video recording of the December 12, 2012 visit confirms Dr. Severyn's description of the sequence leading to this change in medication. For this visit, Ms. Barrett does not appear to have taken a history or recorded Agent Parkison's blood pressure, and Dr. Zaidi met with Agent Parkison for slightly less than three minutes.<sup>228</sup> For the first minute or so, Dr. Zaidi did not actually look at Agent Parkison, but instead was apparently reviewing his medical chart. 229 While still studying the chart, Dr. Zaidi inquired how Agent Parkison was doing, and Agent Parkison responded

<sup>&</sup>lt;sup>203</sup> *Id.* at 86.

<sup>&</sup>lt;sup>204</sup> Id.

<sup>&</sup>lt;sup>205</sup> *Id.* at 88.

<sup>&</sup>lt;sup>206</sup> Gov't Ex. 3c, folder Tyler UC Visit 3, subfolder AudioVideo—11–14 12, file 094453. Note that Government Exhibit 3c also includes an audio-only recording, which was not discussed by the parties and which contains no information relevant to this matter that is not also available in the audio-video recording.

<sup>&</sup>lt;sup>207</sup> Tr. at 341.

<sup>&</sup>lt;sup>208</sup> Gov't Ex. 3c, folder Tyler UC Visit 3, subfolder AudioVideo—11–14 12, file 094453 at 10:00:26 to 10:02:25; Gov't Ex. Twelve at 18.

<sup>209</sup> *Id.* at 10:00:37 to 10:04:56.

<sup>&</sup>lt;sup>210</sup> Id. at 10:04:56 to 10:06:57.

<sup>211</sup> Id.

 $<sup>^{212}\,\</sup>mathrm{Gov't}$  Ex. Twelve at 11; cf.  $\mathit{Id}.$  at 18.

 $<sup>^{213}</sup>$  *Id.* at 11.

<sup>&</sup>lt;sup>214</sup> Id.

<sup>&</sup>lt;sup>215</sup> Id.

<sup>&</sup>lt;sup>216</sup> Id.

<sup>&</sup>lt;sup>217</sup> Id.

<sup>&</sup>lt;sup>219</sup> *Id.;* Tr. at 341.

<sup>&</sup>lt;sup>220</sup> Tr. at 88–89.

<sup>&</sup>lt;sup>221</sup> Id. at 90-91.

<sup>&</sup>lt;sup>222</sup> Id. at 92.

<sup>&</sup>lt;sup>223</sup> *Id.* at 618, 620.

<sup>224</sup> Id. at 619-20.

<sup>&</sup>lt;sup>225</sup> *Id.* at 620.

<sup>&</sup>lt;sup>226</sup> Id. at 95; Gov't Ex. Nine at 20.

<sup>&</sup>lt;sup>227</sup> Tr. at 95.

<sup>&</sup>lt;sup>228</sup> Gov't Ex. 3d, folder Tyler UC Visit, subfolder AudioVideo—12–12–12, file 132123 at 13:48:56—13:51:17

<sup>229</sup> Id. at 13:48:56—13:50:18.

that he had been experiencing some "nagging stiffness" and remarked that one of his "buddies" had suggested "Oxy kind of helps him." 230 Without a pause (other than to observe that such a change would be "a lot more dose" and would be more expensive), Dr. Zaidi wrote a prescription for 42 ten mg tablets of OxyContin.231

Dr. Zaidi then engaged Agent Parkison with questions and advice about his blood pressure (although it appears no one recorded Agent Parkison's blood pressure for this visit).<sup>232</sup> In his treatment notes under the "Subjective" section for the visit on December 12, 2012, Dr. Zaidi wrote that Agent Parkison's pain level is "5 on a scale of 0-10," although there is nothing in the medical chart nor the recording that supports this finding.<sup>233</sup> Further, Dr. Zaidi wrote that Agent Parkison "is not tolerating Percocet, which is lasting only a couple of hours and we are going to change that to OxyContin 10 mg three times a day." <sup>234</sup> There was, however, nothing in either the recording or the patient medical records that indicates the Percocet was lasting only a couple of hours nor that Agent Parkison was not tolerating Percocet—only that he had some "nagging stiffness" and a "buddy" said OxyContin helped.235

Dr. Severyn said that requesting OxyContin under these circumstances "raises in my mind, as it does in that of my associates and colleagues, a question of why is this patient asking for a specific medication by name, instead of relying on my expertise to introduce a specific medication. . . ." 236 He said that "these are red flags that I've heard in . . . national medical conferences for a decade or more." <sup>237</sup>

Dr. Severyn next explained there are more rigorous standards that apply in Ohio when using controlled substances to treat pain that no longer can be described as acute but is instead chronic or intractable.<sup>238</sup> After reviewing patient treatment records for treatment during the first twelve weeks, Dr. Severyn stated that by January 2013, "the medical care is entering into that

<sup>230</sup> Id. at 13:49:10—13:50:00; Gov't Ex. Nine at 20. <sup>231</sup> Id. at 13:49:00—13:50:00; Gov't Ex. Nine at 20;

portion that the statutes in Ohio consider as protracted prescribing." 239 According to Dr. Severyn,

At that point, there is a much higher level of service reflected by documentation that needs to take place. Some of those [include an] evaluation of what is the current employment history, what is the activity of daily living. . . . Is the treatment plan justified? [W]hat is the effectiveness of the treatment plan? That is not recorded here.<sup>240</sup>

Dr. Severyn explained that by the time the protracted prescribing of controlled substances has begun, "the diagnosis needs to be substantiated by the physical findings and my opinion is that they are not, and it needs to be substantiated by the history, and my opinion is that it is not." 241

Because Dr. Zaidi had been treating Agent Parkison for more than twelve weeks by January 2013, "[a]n entirely elevated level of service is called for, which was not evidenced in either the medical chart or the recordings of the office visits from January 2013 forward.242

In reviewing the audio-video recording of the January 9, 2013 visit, I found no examination took place other than the taking of Agent Parkison's blood pressure and oxygen levels by Ms. Barrett.<sup>243</sup> Dr. Zaidi's report of Agent Parkison's subjective symptoms indicates "[h]e is doing better with OxyContin, but it is not strong enough and I am going to increase OxyContin to 15 mg three times a day." 244 Apparently this was based entirely on Agent Parkison stating, "I was wondering if I could get maybe just a little bit stronger" notwithstanding that he reported to Ms. Barrett reductions in his pain level—that at its worst the pain was at level two.<sup>245</sup> Further, despite there being no discussion of Agent Parkison's personal, family, or social history, Dr. Zaidi reported no changes in those histories.<sup>246</sup> Similarly. notwithstanding the absence of any physical examination, Dr. Zaidi wrote that for the subjective examination there

were no abdominal or chest pains, no shortness of breath or dizziness.247 Further, without actually conducting an examination to support these findings, Dr. Zaidi wrote in his objective findings:

Pupils are equal and reacting to light. Skin is warm and dry. Moderate diffuse tenderness and spasm in paralumbar muscles with minimal guarding in forward flexion and extension. Lower extremity examination is normal to sensory and motor testing. His gait is normal.248

During cross examination, Agent Parkison stated that after this visit, he determined no additional visits were warranted.249 He said he had worked cases like these in the past, and in those cases the DEA stopped after the third visit.<sup>250</sup> By the fifth visit with Dr. Zaidi, Agent Parkison "felt it was pretty clear that I had been issued prescriptions other than for a legitimate medical purpose and didn't feel that I needed to continue to go" back for additional treatment.<sup>251</sup> He said by this fifth visit, he had seen that Dr. Zaidi would not question him when he asked for more medication and would not check to see if there was something that was causing him to be in more pain.<sup>252</sup>

According to Dr. Severyn, Dr. Zaidi to this point had failed to make an adequate assessment of Agent Parkison' functional status, or of his activities of daily living.<sup>253</sup> Further, and as was the case in the three prior office visits, while Dr. Zaidi indicates a plan of treatment that includes a "home exercise program," 254 there was no discussion of any home exercises during the office visit, nor is there any evidence that written details of such a program were ever provided to Agent Parkison at any visit.

Dr. Severyn also noted that when a patient reports "stiffness" in the midback, as Agent Parkison did during the visit on January 9, 2013,255 this is significant "because if a patient is describing stiffness as opposed to pain, then whatever treatment plan has brought that patient to that stiffness. [is] a medical success. That's quite good. That sounds like improvement over time. . . . [I]t's an indication that this patient may be getting better, and probably is." <sup>256</sup> Stiffness and pain are, in Dr. Severyn's view, dissimilar, in that "a patient who is complaining of

<sup>&</sup>lt;sup>232</sup> Gov't Ex. 3d, folder Tyler UC Visit, subfolder AudioVideo—12-12-12, file 132123 at 13:50:00-13:50:46; see also Gov't Ex. Twelve at 18 (chart notations indicating blood pressure readings during office visits on October 4, 2012, November 14, 2012, and January 9, 2013, but not for December 12, 2012).

<sup>233</sup> Gov't Ex. Twelve at 10.

<sup>&</sup>lt;sup>234</sup> Id.

<sup>235</sup> Gov't Ex. Nine at 20.

<sup>236</sup> Tr. at 96. 237 Id

<sup>238</sup> Id. at 100-01.

<sup>&</sup>lt;sup>239</sup> *Id.* at 100.

<sup>&</sup>lt;sup>240</sup> Id.

<sup>&</sup>lt;sup>241</sup> *Id.* at 100–01.

<sup>242</sup> Id. at 101.

<sup>&</sup>lt;sup>243</sup> Gov't Ex. 3e at 14:01:29 to 14:02:21. Note that in Government Exhibit 3e at folder labeled Audio 01-09-13 contains a file named 01-09-13, appears to contain an audio-only recording of Agent Parkison's January 13, 2013 office visit. As neither party referred to this recording it has not been reviewed here. Similarly, Government Exhibit 3e in folder AudioVideo 01-09-13 contains a file named Thumbs, which was not referred to by either party and which I was not able to access. Accordingly, it has not been reviewed here.

<sup>&</sup>lt;sup>244</sup>Gov't Ex. Twelve at 9.

 $<sup>^{245}\,</sup>Gov\ensuremath{^{\circ}} t$  Ex. 3e at 14:05:22 to 14:05:57; Gov\ensuremath{^{\circ}} t Ex. Nine at 23-24.

<sup>&</sup>lt;sup>246</sup>Gov't Ex. Twelve at 9.

<sup>&</sup>lt;sup>247</sup> Id.

<sup>&</sup>lt;sup>248</sup> Id.

<sup>249</sup> Tr. at 465-66.

<sup>250</sup> Id. at 466.

<sup>&</sup>lt;sup>252</sup> Id.

<sup>253</sup> Id. at 102-03.

 $<sup>^{254}</sup>$  Gov't Ex. Twelve at 9–12.

<sup>&</sup>lt;sup>255</sup> Id.

<sup>&</sup>lt;sup>256</sup> Tr. at 108–09.

stiffness is a patient for whom pain has been well-controlled. The etiology and cause appears to be in regression or remission and their response to treatment is quite good." 257 When presented with a patient who complains of stiffness but also indicates pain at a level four on a ten point scale, Dr. Severyn stated that a physician can reconcile this by "just asking the patient to be a little more clear" in response to the physician's questions.258

Such a complaint would not justify prescribing controlled substances in the manner shown in the records for Agent Parkison, according to Dr. Severyn, "because there are so many less risky alternatives that can be offered, including muscle relaxants that can be very helpful here, and other approaches to care." 259 Dr. Severyn found, however, no evidence that these alternatives were considered.<sup>260</sup>

In Dr. Severyn's opinion, Dr. Zaidi's controlled substance prescriptions for Agent Parkison were based on a diagnosis that is "completely inaccurate" and "focuses only on controlled substances and not on the several other alternative approaches to care [including] physical therapy, noncontrolled substance medication, [and] the medications in several different classes." 261 He also noted that by January 2013, there was no proper informed consent obtained by Dr. Zaidi for this patient.262 Dr. Severyn acknowledged the form Agent Parkison signed on September 11, 2012 (at the start of his treatment) states, "I consent at this time for treatment with medications and therapeutic procedures." 263 According to Dr. Severyn, however, this does not constitute informed consent, as it "does not sufficiently describe the risks that can go along with using a controlled substance on a regular basis," including "delayed breathing, slowed breathing, risk of overdose, risk of drug withdrawal, risk of diversion of medications, risk of becoming addicted, risk of being a victim of theft and home break-in, and the risk actually for the worsening of pain over time . . . . "264

Dr. Severyn noted that by his fourth visit, Agent Parkison asked for OxyContin by name, something Dr. Severyn regarded as a red flag.<sup>265</sup> He explained that "OxyContin has been a

largely diverted and abused medication, and a patient asking for that medicine . . . by name . . . should and would arise suspicion in the mind of a prescribing physician." 266 Further, during the fifth visit, when Agent Parkison asked for an increase in OxyContin, this too would be considered a red flag, given that there was no physical examination conducted at that visit, and given that it appeared the existing treatment plan was "achieving what it had meant to achieve." 267 Dr. Severyn found no evidence, however, that Dr. Zaidi tried to resolve any of these red flags.<sup>268</sup>

When asked how a physician should respond to a patient who sees an advertisement for a particular drug, Dr. Severyn stated that if the drug was a controlled substance, he would "incorporate that into the remainder of the medical decision-making process' although this did not mean the incident would necessarily be noted in the patient's medical record.<sup>269</sup> He added, however, that in none of the three undercover cases did it appear that the patient told Dr. Zaidi he wanted a particular drug because he had seen the drug advertised.<sup>270</sup>

When asked on cross examination about things a physician must do to resolve red flags associated with potential diversion, misuse, or addiction, Dr. Severyn stated that first the physician must observe the patient over time, note the "maturation" of what is observed, and when encountering more than one "element of discontinuity" more than just observation is called for.<sup>271</sup> "The ultimate 'to-do' always is to say, 'You know, this is not a treatment that I am going to continue for this patient.' That's one approach. Another alternative is other medication, physical therapy, [and] referrals, those are important." 272

Dr. Severyn agreed, on cross examination, that there may have been instances where patients have deceived him without his knowledge.<sup>273</sup> He recalled one such instance where he discovered the deception only after evaluating the results of a urine screen—a test he requires at the initial encounter (as does Dr. Zaidi 274), and thereafter at "every encounter" for patients receiving controlled substances

on a protracted basis.<sup>275</sup> He added, however, that Ohio law does not require testing at every encounter, so he would not opine that Dr. Zaidi should have conducted a urine screen each time these patients visited the office.<sup>276</sup> Further, Dr. Severyn noted that by seeing his patients at least once a month, Dr. Zaidi complied with the standard of care in frequency of patient visits, agreeing during cross examination that this practice is another way to help protect against misuse, diversion, or addiction.277

Regarding a patient's decision not to seek treatment (such as a recommended epidural injection) or diagnostic measures (such as an MRI), Dr. Severyn was asked if he recalled whether the patient attributed the decision to cost or an inability to pay.<sup>278</sup> He said he did recall discussions about patients wishing to await the availability of insurance.<sup>279</sup> He noted, however, that "I also see in the record before me, receipts for medical encounters of \$300 cash on a frequent basis." 280 When he stated he thought these were on a monthly basis, he initially indicated that there were at least two such payments made by Agent Parkison.<sup>281</sup> The record, however, does not support this, and instead indicates the \$300 cash payment was made only at the initial visit, and \$95 was charged for all subsequent visits.<sup>282</sup> After this discrepancy was brought to his attention, Dr. Severyn was asked whether he believed these patients could afford MRIs or injections if these were indicated, and he stated he did not agree that the patients could have afforded those procedures.<sup>283</sup>

Dr. Severyn stated that an MRI is helpful in the context of pain medicine, "when it answers, in the mind of the physician . . . what is the cause of this patient's complaints, the etiology of the physical findings and the implication and impact of learning that information upon the recommendation to be made to the patient and the treatment plan to be put into effect." 284 When asked on cross examination whether it was appropriate for Dr. Zaidi to advise Agent Parkison to have an MRI "because of the vague symptom that he has in his lower back," 285 Dr. Severyn said no, and agreed that the fact that no MRI was

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<sup>257</sup> Id. at 259.
258 Id. at 261.
259 Id. at 109.
260 Id. at 109-10.
261 Id. at 103.
262 Id. at 104-05.
<sup>263</sup> Id. at 104-05; Gov't Ex. Twelve at 25.
264 Tr. at 105-06.
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265 Id. at 113.

<sup>266</sup> Id. <sup>267</sup> Id.

<sup>268</sup> Id. at 114.

<sup>&</sup>lt;sup>269</sup> Id. at 199.

<sup>&</sup>lt;sup>270</sup> *Id.* at 280.

<sup>&</sup>lt;sup>271</sup> Id. at 173-74.

<sup>272</sup> Id. at 174-75.

<sup>&</sup>lt;sup>273</sup> *Id.* at 191.

<sup>274</sup> Id. at 193.

<sup>275</sup> Id. at 191-92.

<sup>276</sup> Id. at 194.

<sup>277</sup> Id. at 196. 278 Id. at 187.

<sup>279</sup> Id

<sup>&</sup>lt;sup>281</sup> Id.

<sup>&</sup>lt;sup>282</sup> Id. at 187-88; Gov't Ex. Sixteen.

<sup>283</sup> Tr. at 188.

<sup>284</sup> Id. at 240.

<sup>&</sup>lt;sup>285</sup> Gov't Ex. 12 at 8.

ever performed did not breach the standard of care. 286

On cross examination, Dr. Severyn agreed that one appropriate means of responding to red flags in the context of prescribing pain medication is to use urine drug screens, and he acknowledged that Dr. Zaidi used these screens as part of his prescription practice.<sup>287</sup>

Dr. Severyn next explained why the inaccuracies found in Dr. Zaidi's medical records of Agent Parkison's treatment are important in the review of Dr. Zaidi's prescription practice:

There is inaccuracy and a listing of a more severe level of pain than what the patient is actually voicing during the encounter with staff or with the physician. The diagnosis, the impression that is listed here, the most impressive and important of them, with regards to guiding the patient through treatment, would be the lumbar radiculitis. and that is not justified or substantiated by either the history or the physical examination. Finally, the approach to treatment that relies on only a controlled substance and does not include many of the other approaches, such as non-steroidal antiinflammatory, neuromodulator, tricyclic medications [and] physical therapy. Those are absent. The home exercise program, I found no evidence that that is being provided.

I found, to a large degree, that if I were to have reviewed only the medical record, as it was presented here, I would have arrived at a different opinion than I am able to, having now had the ability to see a transcript and watch an audio/visual recording of what actually occurred during that encounter.<sup>288</sup>

For these reasons, Dr. Severyn opined that Dr. Zaidi's prescriptions of controlled substances for Agent Parkison "were well outside the usual course of professional practice

#### Dr. Zaidi's Treatment of Officer Patrick Leonard (Under the Name Patrick Tock)

Patrick James Leonard has been employed at the Akron (Ohio) Police Department for about 20 years, the last sixteen of which he has been a detective in the narcotics diversion department.<sup>290</sup> In addition, for the past two years Detective Leonard has been assigned to the DEA as a task force officer, serving in an undercover capacity in the investigation of physicians and others suspected of illicit drug transactions.<sup>291</sup> He was trained as a military police officer in the

United States Army, has completed training at the Ohio Police Officer Training Academy, and received training in pharmaceutical diversion through the Ohio Board of Pharmacy.<sup>292</sup>

Detective Leonard participated in the surveillance of Dr. Zaidi's medical office and was a patient in an undercover capacity, under the name Patrick J. Tock.<sup>293</sup> In his role as a patient, Detective Leonard attended six office visits with Dr. Zaidi, and in each visit received prescriptions for controlled substances.<sup>294</sup> Each of these visits were surreptitiously recorded, and both the recordings and the transcriptions of the relevant portions of those recordings are included in our record.<sup>295</sup> He agreed on cross examination that in his undercover capacity, he was engaged in misleading Dr. Zaidi and his staff during these visits.<sup>296</sup> He denied, however, that there was "any trickery involved. We presented a certain set of facts and waited to see if Dr. Zaidi would write prescriptions." 297

In his role as Patrick Tock, Detective Leonard reported that he had stiffness in his lower back.<sup>298</sup> In his initial interview with Christy Barrett, Detective Leonard reported pain levels of between three and four on a ten-point scale, denying any pain in his legs.<sup>299</sup> He also denied ever being treated for this condition, and denied ever having an MRI or x-ray with respect to the condition.<sup>300</sup> At the conclusion of the initial office visit, he obtained from Dr. Zaidi a prescription for 42 tablets of Percocet five mg.301 According to Detective Leonard, at no time did Dr. Zaidi suggest any treatment for his condition other than controlled substances, nor did Dr. Zaidi suggest physical therapy, exercise, or any other non-medication treatment.302 He said Dr. Zaidi did recommend that he obtain an MRI, providing to Detective Leonard the name of a provider whose charges for this service were reduced for persons, like Detective Leonard, who lacked health insurance.<sup>303</sup> Despite this recommendation, Detective Leonard returned to Dr. Zaidi's office five more times without obtaining an MRI, and on each occasion Dr. Zaidi prescribed him

controlled substances.<sup>304</sup> According to Detective Leonard, while Dr. Zaidi did conduct a physical examination during the first office visit, he conducted no physical examinations during any of the subsequent visits.<sup>305</sup>

As was the case with his review of Agent Parkison's treatment, Dr. Severyn reviewed the medical charts, transcripts, and recordings 306 relating to Dr. Zaidi's treatment of Officer Leonard during six visits to that office. 307 And as was the case with the records of treatment of Agent Parkison, Dr. Severyn noted material differences between what appears in Officer Leonard's written medical chart and what actually occurred during Dr. Zaidi's treatment of the patient.

In the "History and Physical Examination" for the visit on October 23, 2012, Dr. Zaidi reported the patient's "pupils are equal and reacting to light." 308 Dr. Severyn stated that an examination of pupil reaction to light "was not part of the physical examination that I saw undertaken." 309 He explained that "[r]eactive to light' means "that the lighting characteristics in the room changed significantly enough that an evaluation of that could be done." 310 This could be done either by shining a light directly into each of the patient's eyes, or directing the patient's head to a window and back, to see if each pupil independently and to some degree in a coordinated fashion would react to light." 311 Dr. Severyn said he did not see such an examination take place in any of Officer Leonard's office visits where video recordings were part of our record.312

I note that of the recordings included in Government Exhibit Four, audiovisual recordings were available only for the examinations of Officer

<sup>&</sup>lt;sup>286</sup> Tr. at 234.

<sup>287</sup> Id. at 175.

<sup>&</sup>lt;sup>288</sup> *Id.* at 107–08.

<sup>289</sup> *Id.* at 104.

<sup>290</sup> Id. at 553.

<sup>&</sup>lt;sup>291</sup> *Id.* at 554–55.

<sup>&</sup>lt;sup>292</sup> *Id.* at 555.

<sup>&</sup>lt;sup>293</sup> Id. at 555–56.

<sup>&</sup>lt;sup>294</sup> Id. at 556-64.

<sup>&</sup>lt;sup>295</sup> Id.

<sup>&</sup>lt;sup>296</sup> *Id.* at 588.

<sup>&</sup>lt;sup>297</sup> Id. at 588-89.

<sup>&</sup>lt;sup>298</sup> *Id.* at 567.

 $<sup>^{299}</sup>$  *Id.* at 568–69.

<sup>300</sup> *Id.* at 571.

<sup>302</sup> *Id.* at 572

<sup>303</sup> *Id.* at 572–73.

 $<sup>^{304}\,\</sup>mbox{Id.}$  at 573; Gov't Ex. Thirteen.

<sup>&</sup>lt;sup>305</sup> Tr. at 576–83.

<sup>&</sup>lt;sup>306</sup> The recordings in evidence include Government Exhibits 4a through 4f. Government Exhibit 4a contains two folders, both having to do with Officer Leonard's visit to Dr. Zaidi's office on October 23, 2012. One folder, labeled Audio 10-23-13, consists of one file, identified as CCR 0001. The other folder, identified as AudioVideo 10-23-12, has seven files. Four files, identified as 125939, 130541, 130611, and 132851, contain no information material to this administrative matter. The files identified as 130617 and 135848 depict preliminary stages of an office visit on October 23, 2012, but do not include Dr. Zaidi's examination of Officer Leonard (which apparently was captured only by audio recording). It also contains a file identified as Thumbs, which I was unable to access and which has not been referred to by either party, and thus is not part of my review of this record.

<sup>&</sup>lt;sup>307</sup> Tr. at 115.

<sup>308</sup> Gov't Ex. Thirteen at 9.

<sup>&</sup>lt;sup>309</sup> Tr. at 115–16.

<sup>310</sup> Id. at 126.

<sup>&</sup>lt;sup>311</sup> *Id*.

<sup>312</sup> *Id.* at 126–27.

Leonard conducted on December 13, 2012, and February 21, 2013. Although Dr. Zaidi reported the results of light reaction examinations in those two reports and in the examinations conducted on October 23, 2012; November 15, 2012; January 10, 2013; and March 21, 2013,313 there were no video recordings of these four examinations.314

For the examinations conducted on December 13, 2012 and February 21, 2013, it is possible to confirm (and I do confirm) that no examination took place that would provide Dr. Zaidi with objective evidence to support these exam findings,315 but I do not resolve whether examinations took place on October 23, 2012; November 15, 2012; or January 10 or March 21, 2013, 316

I find, however, that Dr. Zaidi's determination to remain silent in the face of testimony tending to show no examinations took place gives rise to a negative inference, one that supports a finding that his examinations on November 15, 2012; January 10, 2013; and March 21, 2013, were substantially similar to those shown in the videos of examinations on December 13, 2012 and February 21, 2013, and do not support the findings he reported in these medical records. It is unclear, however, what examinations, if any, took place on the first visit, on October 23. 2012.317

Dr. Severyn noted that Officer Leonard reported a dull ache affecting the low back during his initial visit, at level three to four on a ten-point scale, without weakness and without numbness going into the legs. $^{318}$  In Dr. Severyn's opinion, this history would support a diagnosis of lumbago, but does not support Dr. Zaidi's diagnosis of radiculitis.<sup>319</sup> As noted above, Dr. Severyn explained that radiculitis calls for "pain arising in the lumbar spine and clearly following the pathway of a

nerve going down into the lower extremity." 320 As was the case with Dr. Zaidi's diagnosis of Agent Parkison, Dr. Severyn said not only is the diagnosis of radiculitis for Officer Leonard inaccurate, "it's blatantly inaccurate." 321

In addition to concerns regarding Dr. Zaidi's written impressions, Dr. Severyn remarked that the patient presented red flags that went unresolved by Dr. Zaidi. One such red flag arose when the patient was unable to produce identification after the initial visit.322 The patient's past drug use also raised a red flag: "It's concerning here that the patient, already describing to the physician that the patient has taken some pain medication from his wife, and that it has helped, but that the patient is not able to describe the name of the medication that his wife is taking and that his wife provided to him." 323

According to Dr. Severyn, after Officer Leonard admitted to using his wife's pain medication, Dr. Zaidi should have obtained more information. 324 Calling it "an element of medical necessity," Dr. Severyn opined that Dr. Zaidi should have attempted to learn when Officer Leonard actually used his wife's  $medication.^{325}$ 

Dr. Severyn explained that while Dr. Zaidi did use urine drug screens as part of his prescription practice, the screen would be useful here if Dr. Zaidi could determine when Officer Leonard actually took his wife's medication. "I think that what is so missing [about] this red flag, about receiving medication from the wife, is we all have no idea when that event would have been said to have occurred. But if it would have been said to have occurred the past day or so, its absence on the urine screen would have been an important red flag. Its presence would be just as important." 326

Also of concern with this patient, according to Dr. Severyn, was the patient's request after the initial visit for an increase in oxycodone; and on the fourth visit the patient's request for Opana.327 This latter request was "a huge flag," because, according to Dr. Severyn, Opana "is a drug that is becoming more commonly diverted. It is because Opana is twice as strong, milligram per milligram, in its effects on the mind, as is the drug Oxycodone,

[which is] present in Percocet and was present in OxyContin."  $^{328}$  Detective Leonard expressed a similar concern regarding Opana, testifying that "[i]t's a highly abused narcotic. We're having a problem with it on the street. High resale." 329 According to Dr. Severyn, there is, however, no evidence that Dr. Zaidi either recognized or sought to resolve these red flags.330 After confirming during cross examination that Dr. Zaidi ended up not prescribing Opana, Dr. Severyn said he believed this to be the appropriate decision.<sup>331</sup>

Dr. Severyn noted that at the initial visit, when Officer Leonard produced only a photocopy of his license (under the pretense that the original had been seized recently by the police), there was some mention that he would need to produce a license at the next visit,332 but there is no evidence that anyone from Dr. Zaidi's office followed through on this at any subsequent office visit.333 Considering the red flags present here, Dr. Severyn stated that it "did not appear that there was significant or sufficient attention to the known indications of abuse or diversion that we've been referring to here as red flags." 334

Beyond these red flags, Dr. Severyn opined that even under a diagnosis of lumbar radiculitis, "[t]his patient has not had benefits of a more conservative plan of treatment. Modification of activities, non-controlled substances, physical therapy are the big three, the main important components of treatment that have to, over a period of several weeks, not result in an improvement" before resorting to controlled substances as treatment for pain.335 He noted further that while the plan of treatment included encouragement for the patient to get an MRI done of the lumbar spine,<sup>336</sup> in Dr. Severyn's view a pain management specialist "would appreciate that an MRI is not indicated at this time, with this patient and with this set of conditions, even were those conditions, as shown in the medical record, accurate." 337 He explained that even if

<sup>313</sup> Gov't Ex. Thirteen at 9, 12-16.

<sup>314</sup> See Gov't Ex. Four

<sup>315</sup> See Gov't Ex. 4c, folder Leonard UC3, AudioVideo 12-13-12, file 083000 at 8:38:52-8:40:31; Gov't Ex. 4e, folder AudioVideo 02-21-13, file 2013-02-21 at 8:58:27-9:00:19

<sup>316</sup> See Government Exhibits 4a, 4b, and 4d, In Government Exhibit 4b, when I attempted to open the file AudioVideo 142205 in the AudioVideo folder, the file would not play, and instead a message appeared stating "Windows Media Player cannot play the file. The player might not support the file type or might not support the codec that was used to compress the file." Accordingly, the only recording of this visit was contained in the audio-only file identified as CCR 0005, found in the folder labeled Audio 11-15-12. In Gov't Ex. 4d, the only file provided by the Government was an audioonly recording labeled 1-10-13 in a folder labeled Audio 01-10-13.

<sup>317</sup> See Gov't Ex. 4a, folder Audio 10-23-12, file CCR 0001 at 49:44-56:00.

<sup>318</sup> Tr. at 117.

<sup>319</sup> Id.; Gov't Ex. Thirteen at 9.

<sup>320</sup> Tr. at 117.

<sup>321</sup> Id. at 118.

<sup>322</sup> Id. at 131.

<sup>323</sup> Id. at 117.

<sup>324</sup> Id. at 176. 325 Id

<sup>&</sup>lt;sup>326</sup> Tr. at 177.

<sup>327</sup> Id. at 134.

 $<sup>^{329}</sup>$  Id. at 578. Detective Leonard testified that Opana 40 mg costs between \$4 and \$5 per tablet and sells for \$50 per tablet on the street, whereas 5/325 mg Percocet costs \$.50 per tablet and sells for between \$8 and \$10 per tablet. Tr. at 615.

<sup>330</sup> Id. at 135.

<sup>331</sup> Id. at 200-01.

<sup>332</sup> See Gov't Ex. 4a at folder AudioVideo 10-23-12, file 130617 at 13:17:13 to 13:17:27; Gov't Ex.

<sup>&</sup>lt;sup>333</sup> Tr. at 135.

<sup>334</sup> Id. at 135-36.

<sup>335</sup> Id. at 118.

<sup>336</sup> Id.; Gov't Ex. Thirteen at 9.

<sup>337</sup> Tr. at 118-19.

an MRI was taken and indicated a significant abnormality associated with lumbar pain,

[T]he treatment of that abnormality probably would not have taken place because it would not be medically necessary. What is medically necessary is [based on] what does the patient have? How is this affecting quality of life, employment, social history? How is the patient responding to the least risky forms of treatment? <sup>338</sup>

Dr. Severyn stated that he reviewed each of the recordings of Officer Leonard's follow-up visits with Dr. Zaidi, and saw no evidence of any subsequent physical examinations, raising doubts about the validity of the diagnoses appearing in the reports of those visits.339 Specifically, he saw no evidence of an examination that would support a finding that the patient's pupils were "equal and reacting to light" <sup>340</sup> because there was no examination of the pupils with light; 341 there was no touching of the patient, and "one can only identify and find tenderness by touching the patient;" 342 there was no evidence of Dr. Zaidi touching Officer Leonard to examine the lumbar spine; 343 there was no examination that would support a finding of "moderate diffuse tenderness and spasm in paralumbar muscles with minimal guarding in forward flexion and extension;" and there was no examination that would support a finding regarding motor and sensory functions of the lower extremity, $^{344}$  as such testing "did not occur." 345 Considering these inconsistencies, Dr. Severyn opined that "when a medical record displays the performance of actions that did not occur, the entire validity of the record becomes subject to extreme doubt and questioning." 346

During cross examination, when it was noted that Dr. Zaidi issued an order prescribing an MRI, Dr. Severyn stated that the MRI "became part of the medical treatment plan, and the patient's lack of follow up of the medical treatment plan is yet another red flag." <sup>347</sup> Thus, while he opined that an MRI for this patient was not medically indicated by the patient's history, the physical examination, and the duration of the problem, the patient's failure to follow the order needed to be taken into account by Dr.

<sup>338</sup> *Id.* at 120–21.

Zaidi. <sup>348</sup> He agreed, however, that Dr. Zaidi could take into account the patient's representations of not having insurance or funds sufficient for such testing, when evaluating the patient's noncompliance with the MRI order. <sup>349</sup> He also agreed that a similar order was written during Dr. Zaidi's treatment of Agent Parkison. <sup>350</sup>

At the same time, however, Dr. Severyn thought that these patients had paid \$300 for their initial office visits and were paying \$95 for each subsequent visit.351 When asked whether there was anything suspicious about a patient's willingness to pay that kind of money for specific drugs while refusing to pay \$200 for a cortisone shot or \$350 for an MRI, Dr. Severyn stated, "I believe that is an indication of possible activity, intent or use or misuse, that's not in keeping with what the intended role of that medication is, in the doctor's treatment plan" and is "very suspicious and it is a red flag." 352

Dr. Severyn noted that as was the case with his treatment of Agent Parkison, when Officer Leonard's treatment extended beyond twelve consecutive weeks, treatment is considered to be on a protracted basis. The plan of treatment here, however, did not consider alternative and less risky medications than controlled substances; did not include physical therapy; and while the written plan "includes a notation for [a] home exercise program . . . the rest of the evidence does not provide a mechanism whereby that was ever put into place." 354

Dr. Severyn explained the significance of a course of pain medication that extends beyond twelve weeks. Under Ohio Administrative Code section 4731–21–02, when it appears that a patient will be treated with pain medication for twelve weeks or longer, "there better be quite a bit of substantiation behind it, and [the] intensity of service needs to justify the continued use of that medication." 355 Even though a physician will not always know at the start of treatment that a patient's treatment will last twelve weeks or longer, the regulation provides that if somebody needs controlled substances that long, greater documentation is needed than would be the case when a person is treated for acute pain on a short-term basis.<sup>356</sup>

Thus, while a physician may treat a person with acute pain without inquiring into social history, work employment, activities of daily living, and the like, while still meeting the standard of care, such inquiries are required when it becomes clear to the physician that the pain is chronic,<sup>357</sup> rather than acute. Once it appears the pain is chronic or intractable, the physician is required to determine what needs to be done differently in treating the patient for pain under Ohio's administrative rules.<sup>358</sup>

Dr. Severyn also noted the absence of information regarding the patient's functional capacities.<sup>359</sup> After noting the patient indicated employment as a delivery driver, Dr. Severyn said he found no evidence that Dr. Zaidi ever inquired about the degree to which the patient's pain symptoms interfered with this employment or inquired about whether the pain interfered with daily activities, family life, or social activities.<sup>360</sup>

Dr. Severyn expressed the opinion that in prescribing controlled substances for Officer Leonard, Dr. Zaidi did so without having a legitimate medical purpose, because the patient's medical complaints did not justify the use of a controlled substance.<sup>361</sup> He stated that based on what he observed in the recordings of these office visits, "the prescribing that took place here was not prescribing for a legitimate medical purpose and was not in the usual course of professional practice." <sup>362</sup>

#### Dr. Zaidi's Treatment of Officer Shaun Moses (Under the Name Shaun Chandler)

Shaun Moses is a Special Agent with the DEA, working out of the DEA's Cleveland, Ohio office. 363 As a Special Agent, he enforces provisions of the Controlled Substances Act, and has done so for more than eight years. 364 He has a bachelor's degree in political science from Hiram College, and has completed the sixteen-week training course at the DEA Academy in Quantico, Virginia. 365 On cross examination, he agreed that included in his training for undercover work were "block[s] of instruction" to help him deceive the target of the

<sup>339</sup> *Id.* at 121.

<sup>340</sup> Id.

<sup>&</sup>lt;sup>341</sup> *Id.* at 122.

<sup>&</sup>lt;sup>342</sup> *Id*.

<sup>343</sup> *Id*.

<sup>344</sup> Gov't Ex. Thirteen at 9.

<sup>345</sup> Tr. at 122, 127.

<sup>346</sup> Id. at 121.

<sup>347</sup> *Id.* at 270.

<sup>348</sup> Id. at 266-67.

<sup>349</sup> Id. at 267.

<sup>350</sup> *Id.* at 271.

 $<sup>^{351}</sup>$  *Id.* at 277.

 $<sup>^{352}</sup>$  *Id.* at 278.

<sup>353</sup> *Id.* at 125.

<sup>&</sup>lt;sup>354</sup> *Id.* at 125–26. <sup>355</sup> *Id.* at 286.

<sup>356</sup> Id. at 286-87.

<sup>357</sup> Id. at 287-88.

<sup>358</sup> Id. at 288.

<sup>359</sup> Id. at 129-30.

<sup>&</sup>lt;sup>360</sup> Id.

<sup>&</sup>lt;sup>361</sup> *Id.* at 128.

<sup>362</sup> *Id*.

<sup>&</sup>lt;sup>363</sup> *Id.* at 473.

<sup>364</sup> Id. at 474.

<sup>365</sup> *Id.* at 475.

investigation.<sup>366</sup> He said the goal of the undercover work was to see Dr. Zaidi and after "giving as little information as possible and being as vague as possible, see what he would prescribe you." 367

Agent Moses visited Dr. Zaidi for treatment on five occasions, under the name Shaun Chandler.368 He identified the recordings made during these visits, and the transcripts made based on these recordings.<sup>369</sup> In each of these visits, Agent Moses obtained prescriptions for controlled substances from Dr. Zaidi. 370

Agent Moses described the physical examination performed by Dr. Zaidi in the first visit. Dr. Zaidi directed Agent Moses to roll up his left pant leg, at which point Dr. Zaidi "squeezed my knee a little bit," then directed Agent Moses to walk on his heels and toes, bend over to touch his toes, straighten his leg while seated, and respond to questions about the presence of back pain.<sup>371</sup> He told Dr. Zaidi he worked for the Village of Gates Mills, doing "[a] lot of manual labor type stuff." 372 According to Agent Moses, at no time did Dr. Zaidi examine his neck, shine a light into either eye, or touch his abdomen.<sup>373</sup> Agent Moses said this was the only visit during which Dr. Zaidi conducted any kind of physical examination.374

As was the case with his review of Dr. Zaidi's treatment of Agent Parkison and Detective Leonard, Dr. Severyn reviewed the recordings, transcripts, and medical records regarding Dr. Zaidi's treatment of Agent Moses as Shaun Chandler.375 And, as was the case in the other two undercover agents' medical records, Dr. Severyn found inaccuracies in the written reports of treatment, when compared with what he observed when watching the video recordings of treatment.376

During the visit on January 29, 2013, Agent Moses presented as having left knee stiffness, which he indicated to Dr. Zaidi was dull and aching, and which he said was at worst four on a ten point scale, and was presently two on that same scale.377 He told Dr. Zaidi he had no prior trauma to the knee, and thus far treated it with "a couple of aspirin" but nothing more.<sup>378</sup> Based on this history

366 Id. at 513.

and examination, Dr. Zaidi suggested Agent Moses get a cortisone shot, which Agent Moses deferred, indicating "I'll get back to you." 379 In response, Dr. Zaidi prescribed Vicoprofen, a controlled substance that is a mixture of Vicodin and ibuprofen.<sup>380</sup>

When asked on cross examination whether a physician acting within the standard of care must decline to provide medical services to a patient who lacks records of prior medical treatment, Dr. Severyn said if there are no prior records then it would not be a breach of the standard of care, nor would it be unusual, as "[t]here will always be a case in which a physician is seeing a patient for the patient's first event of a condition associated with pain." 381 He also opined that physicians "are reasonably entitled to approach a patient as being truthful and representing true facts, as they are described."382

Central to Dr. Severyn's analysis were reports of examination contained in the typed notes appearing in the "History and Physical Examination" report found in the patient's medical records.383 Dr. Severyn compared what appears in this written report of examination with what he saw in the video recording of the office visit, and reported inaccuracies in the report.

Included in these inaccuracies were notations that the patient was "oriented times three," which Dr. Severyn explained meant that the patient was oriented as to person, place and time.384 Dr. Severyn stated these were not formally evaluated during the examination conducted by Dr. Zaidi. 385 He said blood pressure was formally evaluated, but the pupil reaction to light test was not performed, nor was there any examination of the oral mucosa nor the cranial nerves—all of which were reported as being performed in Dr. Zaidi's written report.386

As Dr. Severyn noted, Dr. Zaidi's written report of the physical examination states the patient's thyroid gland is not enlarged and there is no cervical or axillary lymphadenopathy, but at no time did Dr. Zaidi palpate the lymph or thyroid glands.<sup>387</sup> Dr. Zaidi wrote that there was "no tenderness in his cervical, parathoracic, or paralumbar

muscles" yet there was no touching of the area superficial to the cervical spine and no testing of the paraspinal lumbar muscles.<sup>388</sup> Dr. Zaidi wrote that the "upper extremity examination is normal to sensory and motor testing with normal range of motion at the upper extremity joints," but testing of those nerves did not take place.<sup>389</sup> Similarly, although Dr. Zaidi did palpate the knee area, he reported "lower extremity examination otherwise is normal to sensory and motor testing," but did not perform a lower extremity sensory and motor examination.390

Having reviewed the video recording, including the time Agent Moses spent with the medical assistant Christy Barrett and the time spent with Dr. Zaidi, I find Dr. Severyn's observations to be supported by substantial evidence. It is clear that Dr. Zaidi instructed Agent Moses to raise his left pant leg, and that he palpated the patellar area of the left leg; and we see Agent Moses extending his leg and, when standing, rise on his toes and then on his heels. 391 This, however, is the extent of the physical examination.

While there is evidence that Dr. Zaidi tested Agent Moses' gait, finding good balance and coordination, and that Agent Moses performed normal heel and toe walking, Dr. Zaidi also indicated finding a "soft and nontender" abdomen, but never palpated the abdomen.<sup>392</sup> Dr. Zaidi indicated "good air entry bilaterally in both longs with normal S1 and S2 heart sounds," but such testing, according to Dr. Severyn, requires the use of a stethoscope, which did not take place.393

When stating the impressions formed from this examination, Dr. Zaidi indicated "knee pain, limb pain, and possible early osteoarthritis of knee." 394 According to Dr. Severyn, given the examination and history present, the impression of possible early

<sup>367</sup> Id. at 514.

<sup>368</sup> Id. at 475-76.

<sup>369</sup> Id. at 476-82.

<sup>370</sup> Id. at 482-85.

<sup>371</sup> Id. at 491-92.

<sup>372</sup> Id. at 492.

<sup>373</sup> Id. at 495.

<sup>374</sup> Id. at 498.

<sup>375</sup> Id. at 140.

<sup>377</sup> Gov't Ex. Fourteen at 17.

<sup>378</sup> Gov't Ex. Eleven at 9.

<sup>&</sup>lt;sup>379</sup> Tr. at 494.

<sup>&</sup>lt;sup>380</sup> Id.

<sup>381</sup> Id. at 264-65.

<sup>382</sup> Id. at 265.

<sup>383</sup> Gov't Ex. Fourteen at 7-8.

 $<sup>^{384}\,</sup> Tr.$  at 140.

<sup>&</sup>lt;sup>385</sup> Id.

 $<sup>^{386}</sup>$  Id. at 140–41; Gov't Ex. Fourteen at 7–8.

<sup>387</sup> Tr. at 141; Gov't Ex. Fourteen at 7; Gov't Ex. 5A, folder AudioVideo 01-29-13, file 2013-01-29 at 13:42:48 to 13:48:21.

<sup>388</sup> Tr. at 141; Gov't Ex. Fourteen at 7; Gov't Ex. 5A, folder AudioVideo 01-29-13, file 2013-01-29 at 13:41:55 to 13:48:21.

<sup>389</sup> Tr. at 141; Gov't Ex. Fourteen at 7; Gov't Ex. 5A, folder AudioVideo 01-29-13, file 2013-01-29 at 13:42:48 to 13:48:21.

<sup>390</sup> Tr. at 142: Gov't Ex. Fourteen at 7: Gov't Ex. 5A, folder AudioVideo 01-29-13, file 2013-01-29 at 13:42:48 to 13:48:21.

<sup>391</sup> Gov't Ex. 5A, folder AudioVideo 01-29-13, file 2013-01-29 at 13:42:48 to 13:48:21.

<sup>392</sup> Tr. at 142: Gov't Ex. Fourteen at 7: Gov't Ex. 5A, folder AudioVideo 01-29-13, file 2013-01-29 at 13:42:48 to 13:48:21.

<sup>393</sup> Tr. at 142-43; Gov't Ex. Fourteen at 7; Gov't Ex. 5A, folder AudioVideo 01-29-13, file 2013-01-29 at 13:42:48 to 13:48:21.

<sup>394</sup> Gov't Ex. Fourteen at 8

osteoarthritis "cannot be substantiated." <sup>395</sup> He explained:

Early arthritis does cause knee pain, but so do many other things in young, healthy patients. Most common are ligament strains, followed by inflammation of the cartilage behind the knee cap, which is different than cartilage between the bones, between the tibia and the femur, which is the real communicated message, when we use the term osteoarthritis of the knee.<sup>396</sup>

Also of concern to Dr. Severyn was the plan of treatment that Dr. Zaidi based on this examination and history. Dr. Zaidi prescribed Vicoprofen, which is a combination of ibuprofen, a nonsteroidal anti-inflammatory, and hydrocodone (or Vicodin), a controlled substance pain medication.397 "[A] more justifiable approach," according to Dr. Severyn, "would have been to use a non-controlled substance analgesic medication, such as Tramadol." 398 Missing from the plan, according to Dr. Severyn, is any mention of the role the patient's daily activities should play in the treatment plan: "[T]here is no reference to a change in daily activities, periods of rest, possibly work modification, use of physical therapy or the providing of a home exercise program" with the result that the treatment plan is "very controlledsubstance focused, as its initial approach to care." 399 In Dr. Severyn's opinion, "what has been presented in the portions of the record that did take place in the examination room does not justify prescribing a controlled substance, not at that time of the patient's care, for those conditions." 400

Agent Moses returned for an office visit on February 12, 2013, which was preserved in an audio-video recording, the contents of which have been transcribed. 401 During this visit, Dr. Zaidi spent approximately 140 seconds in the room with Agent Moses. 402 At no time during this visit did Dr. Zaidi touch Agent Moses, nor did he have Agent Moses perform any diagnostic actions. 403 As Dr. Severyn indicated, there was no physical examination performed during this visit. 404 Nevertheless, Dr. Zaidi prepared a report of physical examination that

included findings that could not be supported by his examination of this patient. Dr. Severyn stated that unsupported findings appearing in Dr. Zaidi's report of this examination included pupil reactivity to light, tenderness in the joint, the absence of redness and swelling, range of motion, and normal motor and sensory testing of the leg.405 Similarly, while the plan of treatment for this visit indicated home exercise as a feature of treatment, no home exercise program had been provided.406 Agent Moses confirmed that throughout his visits there was never any discussion of physical therapy, no discussion about doing exercises at home, nor was he ever given any written materials relating to home exercise.407

Dr. Severyn also noted with some concern the subjective report for this visit, where Dr. Zaidi states that Agent Moses was complaining of both knee and leg pain, and that the pain level he was experiencing was between four and five. 408 While the record supports a complaint of knee pain, there is nothing in the record that supported a complaint of leg pain. Further, as Dr. Severyn correctly observed, Agent Moses reported pain levels only to the office assistant, not to Dr. Zaidi on this visit, and the assistant accurately reported that the pain levels described by Agent Moses were between two and three.<sup>409</sup> There is nothing in the record that would support an examination report of pain level five that Dr. Zaidi reported in his medical history for this visit, Agent Moses stated the written report by Dr. Zaidi, indicating a reported pain level of four or five, was not accurate.410

Agent Moses' third visit to Dr. Zaidi's office, on March 11, 2013, lasted two minutes and 25 seconds <sup>411</sup> and was recorded by audio and audio-video recordings. <sup>412</sup> According to Dr. Severyn,

objective findings that could not be supported by the actual examination of Agent Moses in the visit on March 11, 2013 included:

[T]he reactivity of the pupils to light, the diffuse tenderness of the left knee, when the left knee is touched. The absence of redness or swelling being reported in here requires a physical examination to be performed, which was not. Range of motion testing requires a classic evaluation, or at least flexion and extension, and it was not [done]. The lower extremity examination being normal with both motor and sensory testing is reported here, and that did not occur.<sup>413</sup>

Here again, Dr. Severyn noted that although it appears as a term of the treatment plan, there is no evidence suggesting Dr. Zaidi provided Agent Moses with information about a home exercise program. 414 Having seen the audio-video recording of this office visit, I find there is substantial evidence to support Dr. Severyn's finding that Dr. Zaidi did not examine Agent Moses sufficiently to support the findings appearing in this history and examination report.

In his review of Agent Moses' fourth office visit, on April 9, 2013, Dr. Severyn noted many of the same concerns—that Dr. Zaidi's written history and report of physical examination reported conditions that could be legitimately entered only if a physical examination had been performed. Having reviewed the recording of the visit on April 9, 2013 (which lasted three minutes and 33 seconds),415 I concur with Dr. Severyn's conclusion that Dr. Zaidi did not conduct a physical examination that would support the written findings in his report.416

In his review of the fifth and final visit by Agent Moses on May 6, 2013, Dr. Severyn noted the same concerns as were presented in his discussion of the fourth visit.<sup>417</sup> Again, after reviewing the audio-video recording of this visit, I find substantial evidence to support Dr. Severyn's findings based on a demonstration that Dr. Zaidi performed

<sup>&</sup>lt;sup>395</sup> Tr. at 143.

<sup>&</sup>lt;sup>396</sup> Id.

<sup>397</sup> Id. at 144; Gov't Ex. Fourteen at 8.

<sup>&</sup>lt;sup>398</sup> *Id.* at 144.

<sup>&</sup>lt;sup>399</sup> *Id.* at 144–45.

<sup>400</sup> *Id.* at 145.

 $<sup>^{401}</sup>$  Gov't Ex. 5b; Gov't Ex. Fourteen at 11–15; Gov't Ex. Eleven at 14–18.

<sup>&</sup>lt;sup>402</sup> Gov't Ex. 5b, folder Moses UC 2, subfolder AudioVideo 02–12–13, file 2013–02–12 at 14:43:30 to 14:45:49.

<sup>&</sup>lt;sup>403</sup> *Id*.

<sup>&</sup>lt;sup>404</sup> Tr. at 145.

<sup>405</sup> Id. at 145-46.

 $<sup>^{406}</sup>$  Id. at 149; Gov't Ex. Fourteen at 12.

<sup>&</sup>lt;sup>407</sup> Tr. at 546.

 $<sup>^{408}</sup>$  Id. at 148; Gov't Ex. Fourteen at 12.

 $<sup>^{409}\,\</sup>mathrm{Tr.}$  at 148; Gov't Ex. Eleven at 14–15; Gov't Ex. Fourteen at 16.

<sup>&</sup>lt;sup>410</sup> Tr. at 499.

<sup>&</sup>lt;sup>411</sup>Gov't Ex. 5c, folder Moses UC Visit, subfolder AudioVideo, file 03–11–2013 at 14:43:15–14:45:37.

<sup>412</sup> Gov't Ex. 5c; Gov't Ex. Eleven at 19–22; Gov't Ex. Fourteen at 11. Note the audio-video recording includes Christy Barrett preparing Agent Moses for his visit with Dr. Zaidi. Some of the video images of this exchange were obscured, as the recording device apparently became improperly positioned. These limitations did not materially affect my ability to discern the nature of Ms. Barrett's preparation, as the audio portion of this interview was intact. Similarly, approximately five seconds of Dr. Zaidi's visit with Agent Moses was obscured either by Agent Moses' hand or his clothing. Immediately before and after this period of obstructed view, Dr. Zaidi was seated away from

Agent Moses, mostly facing the wall while reading and writing notes, while Officer Moses was seated on the other side of the office. Notwithstanding this brief period of obstruction, the recording is sufficiently intact to permit me to conclude, as I do, that at no time during this office visit did Dr. Zaidi come into close proximity to or contact with Agent Moses

<sup>413</sup> Tr. at 149-50.

<sup>414</sup> Id. at 150; Gov't Ex. Fourteen at 11.

<sup>415</sup> Gov't Ex. 5d, folder AudioVideo, file SM-04-09-13 at 9:37:25 to 9:40:58; Gov't Ex. Eleven at 23-27. As was the case with the recording of March 11, 2013, a portion of the time Christy Barrett spent with Agent Moses lacks a video picture, but the audio portion is unaffected.

<sup>&</sup>lt;sup>416</sup> Tr. at 151.

<sup>417</sup> Id. at 151-53.

no physical examination of Agent Moses during this visit.<sup>418</sup> Dr. Zaidi conducted the visit, which lasted 80 seconds,<sup>419</sup> while standing at the head of the examination table, while Agent Moses remained seated at all times, without any physical contact between the two.<sup>420</sup>

I also concur with Dr. Severyn's observation that although his treatment plan indicates he prescribed a home exercise program, Dr. Zaidi failed to propose a home exercise plan for this patient.<sup>421</sup> Further, Dr. Severyn stated that there was no evidence Dr. Zaidi attempted to determine whether Agent Moses' pain interfered with his daily activities, with his quality of family life, or with social activities.<sup>422</sup>

Dr. Severyn also expressed the opinion that Dr. Zaidi failed to resolve red flags that arose when Agent Moses sought to increase his medication during the fourth visit.423 The specific exchange noted here began when Dr. Zaidi asked if Agent Moses had experienced any changes since the last office visit. After stating that there was stiffness in the knee, Agent Moses told Dr. Zaidi, "I was talking to a guy I work with [who] had like a similar issue, and he said that he tried Percocet and that like knocked it out . . . ." Without hesitating, Dr. Zaidi responded, "Well, that's a dramatic statement. I will write you Percocet but it will not knock it out." <sup>424</sup> After warning that Percocet was "a little stronger" and stating that he thought "the main thing that will come close to knocking it out is [a] cortisone injection in there," Dr. Zaidi noted that Agent Moses has "been going pretty fast here on the medications' during these four visits.425 He warned that "you are going to not get advice from too many friends" regarding what medication is appropriate for the next step, explaining "[t]his is how people get in trouble." 426 Dr. Severyn said Dr. Zaidi's warning that the patient is heading for trouble and should not be getting advice from friends about what medication to take was appropriate.427

According to Dr. Severyn, however, prescribing Percocet four times daily at

this point was not a reasonable solution, and that decision in the face of these red flags "is one that I don't find to be medically in keeping with . . . prevailing standards of care." 428 He said he could find no medical reason for changing Agent Moses' prescription from Vicodin to Percocet.<sup>429</sup> Similarly, when asked whether it appears Dr. Zaidi took into account the risk of addiction and the risk of diversion of controlled substances, Dr. Severyn opined that while the milligram levels prescribed were primarily in the low range, 430 he believed Dr. Zaidi did not take into account the risk of addiction "to an adequate degree,"  $^{\rm 431}$  and did not focus attention on the risk of diversion, focusing instead "on the risk of consumption." <sup>432</sup> Dr. Severyn stated that there needed to be interaction between the patient and physician in order to determine whether changes in medication have to be made, and confirmed there was some interaction between Agent Moses and Dr. Zaidi. 433 Such interaction would need to reflect the patient explaining whether the existing medication is helping or notsomething Dr. Severyn said did take place, but only to a "limited" degree. 434 Dr. Severyn expressed concern, however, that the only reason for changing Agent Moses' prescription for controlled substances was that "a friend tried Percocet for similar symptoms and that it improved." 435 In Dr. Severyn's opinion, changing the prescription upon this history was not at all medically appropriate.436

From this review of Dr. Zaidi's prescription practice concerning Agent Moses, Dr. Severyn stated that in his opinion, "the prescribing of controlled substances in this patient's treatment was not prescribing medication for a legitimate purpose or in the usual course of professional practice." 437

#### **Analysis**

Four core facts compel my determination that it would be inconsistent with the public interest for the Administrator to permit Dr. Zaidi to continue prescribing controlled substances. First, the evidence establishes that Dr. Zaidi repeatedly prescribed controlled substances under conditions that warranted further

investigation and, in the absence of such investigation, were not for a legitimate medical purpose. His decision to prescribe narcotic pain medication to three undercover agents despite the presence of numerous red flags constituted a material breach of the duties owed by physicians practicing under the Controlled Substances Act, and his prescription practice in these three cases did not meet Ohio's requirements for the distribution of controlled substances.

Second, the evidence establishes that Dr. Zaidi lacks the experience and insight needed to participate in the controlled substance distribution system. His decision to manage a pain clinic using a protocol that permitted the issuance of prescriptions for controlled substances without conducting physical examinations threatens the public safety. Either through ignorance or deliberate indifference, Dr. Zaidi's decision to establish such operations indicates he lacks sufficient insight and experience to be trusted to participate in the controlled substance distribution process.

Third, the evidence establishes that Dr. Zaidi misrepresented the scope and character of both the physical examinations he performed and medical histories obtained during office visits with three DEA undercover agents. While such a practice may well constitute fraud, the Government made no claim of fraud here. Instead, it asserts that this feature of Dr. Zaidi's prescription practice constitutes conduct that is not otherwise addressed by the enumerated factors found in 21 U.S.C. 823(f)(1-4) but which nonetheless is conduct that "may threaten the public health and safety.'' 438

Fourth, after the Government presented evidence sufficient to establish that his continued DEA registration would be inconsistent with the public interest, Dr. Zaidi failed to present evidence of an acknowledgement of wrongdoing and a proposal for meaningful remediation. Accordingly, I will recommend that the Administrator revoke Dr. Zaidi's DEA registration and deny any pending application for renewal of the same.

#### Elements of a *Prima Facie* Case

This administrative action began when the DEA's Administrator through her Deputy Administrator issued an order proposing to revoke Dr. Zaidi's DEA Certificate of Registration and ordering him to show cause why that

<sup>&</sup>lt;sup>418</sup> Gov't Ex. 5e, folder Sept 05 2013, subfolder AudioVideo, file 05–06–2013 at 09:55:14–09:56:46 (vital signs and history taken by Ms. Barrett), 09:58:50–10:00:10 (visit with Dr. Zaidi).

 $<sup>^{419}\,</sup>Gov't$  Ex. 5e, folder Sept 05 2013, subfolder Audio Video, file 05–06–2013 at 09:58:50–10:00:10.

<sup>&</sup>lt;sup>420</sup> Id.

<sup>&</sup>lt;sup>421</sup> Tr. at 153.

<sup>422</sup> Id. at 155.

<sup>423</sup> Id. at 156-57.

<sup>424</sup> Gov't Ex. Eleven at 25.

<sup>&</sup>lt;sup>425</sup> Id.

<sup>426</sup> Id

<sup>&</sup>lt;sup>427</sup> Tr. at 275.

<sup>428</sup> Id. at 159-60.

<sup>&</sup>lt;sup>429</sup> *Id.* at 276–67.

<sup>&</sup>lt;sup>430</sup> *Id.* at 202.

<sup>&</sup>lt;sup>431</sup> *Id.* at 160.

<sup>432</sup> Id. at 161.

<sup>&</sup>lt;sup>433</sup> *Id.* at 202.

<sup>434</sup> Id. at 203.

<sup>&</sup>lt;sup>435</sup> *Id.* at 277.

<sup>&</sup>lt;sup>437</sup> *Id.*at 153.

<sup>438 21</sup> U.S.C. 823(f)(5).

registration should not be revoked.<sup>439</sup> The order alleged that Dr. Zaidi distributed controlled substances by issuing prescriptions under conditions that violated provisions in sections 823(f) and 824(a)(4) of Chapter 21 of the United States Code.<sup>440</sup> Thus, in order to revoke Dr. Zaidi's Certificate of Registration, the Government has the burden of establishing, by at least a preponderance of the evidence, that allowing Dr. Zaidi to continue to issue prescriptions for controlled substances is contrary to the public interest.<sup>441</sup>

While the burden of establishing that Dr. Zaidi's certification contravenes the public interest never shifts from the Government, once the Government meets this burden, Dr. Zaidi has the opportunity to present evidence that he accepts responsibility for his misconduct, and has taken appropriate steps to prevent misconduct in the future.<sup>442</sup>

Under the registration requirements found in 21 U.S.C. 823(f), the Administrator is expected to consider five factors in determining the public interest when presented with the actions of a physician engaged in prescribing controlled substances. These factors are:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.<sup>443</sup>

Any one of these factors may constitute a sufficient basis for taking action with respect to a Certificate of Registration. 444 Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether a registration should be rejected. 445

Moreover, although the Administrator is obliged to consider all five of the public interest factors, she is "not required to make findings as to all of the factors." 446 The Administrator is not required to discuss each factor in equal detail, or even every factor in any given level of detail.447 The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest." 448

In making a medical judgment concerning the right treatment for an individual patient, physicians require a certain degree of latitude. Hence, "[w]hat constitutes bona fide medical practice must be determined upon consideration of evidence and attending circumstances." 449

# Factor One—Recommendations of the State Licensing Board

In its post-hearing brief, the Government does not propose to use Factor One as a basis for arguing that the continued registration of Dr. Zaidi is contrary to the public interest.<sup>450</sup> Factor One considers "[t]he recommendation of the appropriate State licensing board or professional disciplinary authority.' Although the recommendation of the applicable state medical board is probative to Factor One, the Administrator possesses "a separate oversight responsibility with respect to the handling of controlled substances" and therefore must make an "independent determination as to whether the granting [or revocation] of [a registration] would be in the public interest." 451

We do not have an express recommendation by the applicable regulators in Ohio. This may be a factor to consider when evaluating the weight to be given to Dr. Severyn's analysis. There is, however, no substantial evidence of a "recommendation" in support of Dr. Zaidi's continued

practice in Ohio; nor is there evidence that the state's medical board elected to evaluate any of Dr. Zaidi's treatment records (or even that it is currently aware of this administrative action).

From the record before me I cannot discern a reason for the Board's inaction, and as such I cannot conclude that its inaction establishes that Dr. Zaidi's prescription practice conformed to Ohio law. Such evidence, standing alone, cannot support a finding under Factor One.

#### Deleted Discussion (Factor Two) Factor Three

Under Factor Three the Administrator is to consider an applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances. <sup>452</sup> Neither the Government nor Respondent has raised any claims pertaining to Factor Three, and there is no evidence that Dr. Zaidi has been convicted of any laws related to dispensing controlled substances. Accordingly Factor Three does not serve as a basis for revoking Respondent's DEA Certificate of Registration.

#### **Factor Four**

Under Factor Four the Administrator is required to consider Respondent's "compliance with applicable State, Federal, or local laws relating to controlled substances." 453 "A prescription for a controlled substance is unlawful unless it has been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice." 454 Departing from the usual course of professional practice can have profound negative consequences. Here, a preponderance of the evidence establishes that with respect to the three undercover agents, Dr. Zaidi prescribed controlled substances without having a legitimate medical purpose and under conditions that fell outside of the usual course of professional practice.

As the Government aptly notes in its post-hearing brief, when she determines whether a practitioner's conduct "exceeds the bounds of professional practice when prescribing controlled substances," <sup>455</sup> the Administrator

<sup>439</sup> ALJ Ex. One.

<sup>&</sup>lt;sup>440</sup> *Id.* at 1.

<sup>&</sup>lt;sup>441</sup> 21 U.S.C. 823(f); 21 U.S.C. 824(a); 21 CFR 1301.44(d)–(e); see also *Steadman* v. *SEC*, 450 U.S. 91, 100–01 (1981).

 $<sup>^{442}\,</sup>Marc$  G. Medinnus, D.D.S., 78 FR 62683–01, 62691–93 (DEA October 22, 2013).

<sup>443 21</sup> U.S.C. 823(f).

<sup>&</sup>lt;sup>444</sup> Robert A. Leslie, M.D., 68 FR 15227–01, 15230 (DEA March 28, 2003).

<sup>&</sup>lt;sup>445</sup> Morall v. DEA, 412 F.3d 165, 173–74 (D.C. Cir. 2005); JLB, Inc., d/b/a Boyd Drugs, 53 FR 43945–

<sup>02, 43947 (</sup>DEA October 31, 1988); see also *David E. Trawick, D.D.S.*, 53 FR 5326–01, 5327 (DEA February 23, 1988).

<sup>&</sup>lt;sup>446</sup> *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall* v. *DEA*, 412 F.3d at 173–74 (D.C. Cir. 2005).

<sup>&</sup>lt;sup>447</sup> *Trawick* v. *DEA*, 861 F.2d 72, 76 (4th Cir.

 $<sup>^{448}\,</sup>Jayam$  Krishna-Iyer, M.D., 74 FR 459–01, 462 (DEA January 6, 2009).

 $<sup>^{449}\,</sup>United$  States v.  $Collier,\,478$  F.2d 268, 272 (5th Cir. 1973).

 $<sup>^{450}\,\</sup>mbox{Government's Proposed Findings of Fact,}$  Conclusions of Law[,] and Argument at 21.

 $<sup>^{451}\,</sup>Mortimer\,B.$  Levin, D.O., 55 FR 8209–01, 8210 (DEA March 7, 1990).

<sup>&</sup>lt;sup>452</sup> 21 U.S.C. 823(f)(3).

<sup>453 21</sup> U.S.C. 823(f)(4).

<sup>&</sup>lt;sup>454</sup> Sun & Lake Pharmacy, Inc., D.B.A. The Medicine Shoppe, 76 FR 24523–02, 23530 (DEA May 2, 2011).

<sup>&</sup>lt;sup>455</sup> Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 22 (quoting *United States v. Moore*, 423 U.S. 122, 142–43 (1975)].

"generally looks to state law." <sup>456</sup> The Government points out that Ohio regulations prohibit a physician from prescribing controlled substances without first "taking into account the drug's potential for abuse, the possibility the drug may lead to dependence, the possibility the patient will obtain the drug for non-therapeutic use or to distribute to others, and the possibility of an illicit market for the drug." <sup>457</sup>

There is evidence, aptly noted in Respondent's post-hearing brief, that Dr. Zaidi did to some extent take into account the risks of abuse and diversion associated with the drugs he was prescribing. Dr. Zaidi, for example, screened all cases using the OARRS protocol, required urine drug screening at the initial visit, prescribed low doses of the narcotics (at least initially), required check-ins every two weeks, warned against taking medication that had been prescribed to others, and described the risks of moving quickly to ever stronger narcotic medication.<sup>458</sup>

No one distinct set of circumstances permits me to determine the extent to which Dr. Zaidi recognized the potential for abuse or diversion when treating the undercover agents. All of the foregoing office protocols may have been instituted to reflect Dr. Zaidi's concern for the potential misuse or diversion of controlled substances. Given Respondent's decision to not testify, however, our record is silent with respect to Dr. Zaidi's mental assessment of these cases. I am thus left to discern what factors Dr. Zaidi took into account when prescribing these drugs based on the contents of the written medical records and on what I heard and saw in reviewing the recordings of the undercover agents' office visits. In doing so, I cannot help but be influenced by the evidence of falsification present in these records. Knowing now what actually occurred during the office visits and comparing that to what Dr. Zaidi wrote in the patient records, I find little reason to believe these protocols were instituted to reduce the risk of abuse or diversion, but were instead instituted to provide some degree of cover for Dr. Zaidi against regulatory action by the DEA, should his records ever by subject to audit.

As the Government correctly points out, in its prehearing statement the Government put Dr. Zaidi on notice

well before the hearing that it intended to question him about his response to these red flags. 459 As a matter of law, the Government is entitled to an inference that had he testified, Dr. Zaidi would have acknowledged fabricating much of the information in the officers' medical records and failing to resolve the red flags identified by Dr. Severyn, and would have acknowledged that his treatment of the undercover agents fell below accepted medical standards.<sup>460</sup> With such an inference occasioned by his silence in the face of independent evidence showing that his practice fell below accepted medical standards, Dr. Zaidi cannot now be understood to have conformed to those standards.

Independent of such an inference, however, the same result is warranted. I have considered the steps taken to resolve red flags identified by Dr. Severyn. As the Government has suggested, Dr. Severyn's conclusion is supported by evidence that Dr. Zaidi failed to resolve numerous red flags the agents presented during their office visits.<sup>461</sup>

Testimony from Dr. Severyn helps to identify what red flags were presented to Dr. Zaidi during these visits. These include, for example, being presented by a patient's request for OxyContin by brand name. 462 Dr. Severyn explained why this conduct needs to be addressed by the prescribing physician, as it indicates that the patient was relying on outside sources (here either friends or family) to chart the course of medication, "instead of relying on my expertise to introduce a specific medication." 463

I give great weight to Dr. Severyn's assessment of circumstances that constitute red flags, given his substantial relevant experience in prescribing controlled substances for treating pain, his understanding of the pressures facing pain medicine physicians, and his familiarity with Ohio's pain management regulations. Thus, when he relates that a pain management patient's request for OxyContin by name has been a red flag for pain management physicians for "a decade or more" I attribute great weight to that opinion. The same was true when Officer Leonard requested Opana, which both Officer Leonard and Dr. Severyn stated was now becoming increasingly diverted and abused.464

While our record shows that Dr. Zaidi did not actually prescribe Opana, it is silent with respect to whether Dr. Zaidi recognized this as a red flag needing resolution.

Similarly, Dr. Severyn considered Agent Moses' request for an increase in medication at the fourth office visit to be a red flag, where the request was based solely on the recommendation of "a guy [Agent Moses] work[s] with" 465 who reported successful treatment using Percocet. 466 I attribute great weight to Dr. Severyn's opinion that these all were unresolved red flags.

To much the same effect was Dr. Zaidi's apparent complacence when a patient sought an increase in the amount of OxyContin being prescribed. Again, there was no evidence that Dr. Zaidi engaged Officer Parkison in any inquiry that would probe why existing levels of pain medication were inadequate. 467 According to Dr. Severyn, given that OxyContin has been so "largely diverted and abused," the failure to make such an inquiry constituted the failure to resolve a relevant red flag. 468

Respondent in his post-hearing brief correctly points out that resolving red flags can take time—a point with which Dr. Severyn concurred. Georgia Specifically, Dr. Severyn opined that a treating source generally will not sufficiently observe and evaluate a patient in one or two visits, but that instead will address red flags over time, with the length of time dependent on the circumstances.

Dr. Severyn added, however, that depending on the indicators presenting as red flags, the physician may have to do more than just wait.<sup>471</sup> There is, however, no evidence that Dr. Zaidi took any action when confronted with these red flags, other than to accede to the requests of his patients to increase the amount of pain medication being prescribed.

Another red flag was the refusal of a patient to obtain an MRI despite the treating physician's order for such imaging. 472 While I agree with Respondent's proposition that MRIs are expensive and cost may have been a factor Dr. Zaidi took into account when faced with this particular red flag, I agree with the opinion expressed by Dr. Severyn in this regard. We have three

<sup>456</sup> Id. (citing Kamir Garces-Mejias, 72 FR 54931–02, 54935 (DEA September 27, 2007) & United Prescription Services, Inc., 72 FR 50397–01, 50407 (DEA August 31, 2007)).

<sup>&</sup>lt;sup>457</sup> Ohio Admin. Code 4731–11–02(C).

<sup>&</sup>lt;sup>458</sup> Post-Hearing Brief of Respondent at 14–19 and citations to the record therein.

 $<sup>^{459}\</sup>mbox{Government's Proposed Findings of Fact,}$  Conclusions of Law[,] and Argument at 28 and citations therein.

<sup>&</sup>lt;sup>460</sup> *Id*.

<sup>461</sup> Id. at 23.

<sup>462</sup> Tr. at 95-96.

<sup>&</sup>lt;sup>463</sup> *Id.* at 96.

<sup>464</sup> Id. at 134, 578.

<sup>&</sup>lt;sup>465</sup>Gov't Ex. Eleven at 25.

<sup>&</sup>lt;sup>466</sup> Tr. at 156–57.

<sup>467</sup> Id. at 113.

<sup>&</sup>lt;sup>468</sup> *Id.* at 113–14.

 $<sup>^{\</sup>rm 469}\, \rm Post\mbox{-}Hearing$  Brief of Respondent at 5 and citations therein.

<sup>&</sup>lt;sup>470</sup> Tr. at 173-74.

<sup>471</sup> Id. at 174-75.

<sup>472</sup> Id. at 185, 266-67.

patients who demonstrated the ability to pay \$300 for their initial visits and \$95 for each of four or five subsequent visits. The refusal of Agent Moses to comply with Dr. Zaidi's recommendation that he pay \$200 for a cortisone shot, and the refusal of Agent Parkison to pay \$350 for an MRI "is very suspicious, and it is a red flag." 473 What I saw in the video recordings of the office visits where Dr. Zaidi made these recommendations leads me to conclude that Dr. Zaidi saw no significance in the undercover agents' refusal to procure these treatments and diagnostic tools. He was indifferent—the patients could comply with his orders or not—but he would continue prescribing controlled substances regardless.

While a patient's request for brand name opiates does not in and of itself compel a conclusion that the patient is seeking to divert or abuse pain medication, the request must be addressed by the treating physician. There is, however, nothing in the record suggesting that Dr. Zaidi regarded these requests for brand-name pain-killers as anomalous or requiring further inquiry. Similarly, a patient's decision not to pursue more conservative treatment (such as cortisone injections) or obtain diagnostic information (such as is available with an MRI) by itself is not conclusive of an intent to abuse or divert narcotics, but such decisions have to be taken into account by the prescribing source. To the extent Dr. Zaidi elected to not dispute Dr. Severyn's thoroughly documented observations, I am entitled to infer that Dr. Zaidi failed to consider the possibility that the undercover agents sought drugs for non-therapeutic reasons or that the drugs he prescribed could have led to dependence. To the extent such a failure indicates a lack of experience, Dr. Zaidi's failure to resolve red flags—standing alone—has been addressed in the Factor Two discussion above. To the extent it led to the issuance of actual prescriptions for controlled substances, Dr. Zaidi's practice violated Ohio law relating to the prescription of controlled substances. 474 In turn, this violation of Ohio law leads to my finding that Dr. Zaidi's continued DEA registration would be inconsistent with the public interest under Factor Four.475

Independent of Dr. Zaidi's failure to resolve red flags is evidence that the diagnoses upon which controlled substances were prescribed cannot withstand scrutiny. I find substantial evidence supports Dr. Severyn's opinion that Dr. Zaidi had no basis for diagnosing either Agent Parkison or Detective Leonard with lumbar radiculitis, given the examinations that supported those diagnoses and given that neither officer complained of pain radiating into the leg.476 I find uncontroverted and persuasive Dr. Severyn's description of the steps needed to establish such a diagnosis; and I find that the examinations of record would not permit such a diagnosis in the ordinary course of professional practice, for the reasons presented by Dr. Severyn. I believe Dr. Zaidi purposely included more serious diagnoses to support prescribing more controlled substances than were medically necessary and to insulate him from DEA investigations, perhaps not realizing that the DEA performs undercover operations that include surreptitious audio-video recordings of patient visits.

I find the evidence establishes that by prescribing controlled substances based on a diagnosis of radiculitis, Dr. Zaidi did so without a legitimate medical purpose. As such, Dr. Zaidi's continued DEA registration would be inconsistent with the public interest under Factor Four.<sup>477</sup>

There is a third basis under Factor Four that warrants evaluation. Apart from failing to resolve red flags and basing controlled substance prescriptions upon an unsustainable diagnosis of radiculitis, Dr. Zaidi failed to comply with Ohio law in the maintenance of his medical records. Under Ohio law a physician prescribing controlled substances must "complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients." 478 Note that this requirement applies to all prescriptions involving controlled substances, regardless of whether the diagnosed condition relates to pain, and regardless of the duration of treatment.479 Thus, it is a requirement arising from the very start of the patient-physician relationship, once the physician determines the need to prescribe controlled substances.

In addition, under this regulation, a medical record of treatment involving controlled substances must "accurately reflect the utilization of any controlled substances in the treatment of a patient and shall indicate the diagnosis and purpose for which the controlled substance is utilized, and any additional information upon which the diagnosis is based." <sup>480</sup> As the Government correctly observed in its post-hearing brief, "Respondent repeatedly fabricated the officers' medical records by exaggerating their pain levels and falsely stating that his 'Plan of Treatment' included 'home exercise' which was never proposed, suggested, nor discussed at any visit." <sup>481</sup>

I found this part of the record particularly troubling. Had I before me only Dr. Zaidi's written medical records of the officers' treatment, I would have reasonably concluded that Dr. Zaidi was responding to complaints of pain that were significantly more severe than what was actually presented during these office visits. Dr. Zaidi's assistant accurately recorded pain levels as they were presented to her by the undercover officers, generally noting pain in the range of two, three, or four on a tenpoint scale. In his typewritten chart, however, Dr. Zaidi indicates pain levels of five, which could not be substantiated by either what the patients said to the assistant or what they said to Dr. Zaidi. The evidence shows Dr. Zaidi misrepresented and exaggerated the patients' complaints of pain.

As Dr. Severyn noted with some concern, once it became clear that Dr. Zaidi exaggerated the patients' reports of pain, and once it became clear that Dr. Zaidi's diagnoses for radiculitis could not be substantiated by the actual physical examinations he performed, "the entire validity of the record becomes subject to extreme doubt and questioning." <sup>482</sup> Similarly, Dr. Zaidi's report of leg pain and early osteoarthritis of the knee in Agent Moses was exaggerated, and the patient never reported limb or leg pain. <sup>483</sup>

Beyond exaggerating the patients' complaints of pain, Dr. Zaidi falsely reported results from tests that were never performed. From my review of the recordings of the undercover officers' visits, I find Dr. Zaidi falsely reported their pupils' reactivity to light, their heart and chest sounds, the condition of their abdomens, their lower extremity sensory and motor condition, and their limbs' range of motion. Further, I find Dr. Zaidi falsely described prescribing conservative measures (including home exercise programs) in their medical

<sup>473</sup> Id. at 278.

<sup>474</sup> Ohio Admin. Code 4731-11-02(C).

<sup>475 21</sup> U.S.C. 823(f)(4).

<sup>&</sup>lt;sup>476</sup> Tr. at 77–78, 118.

<sup>&</sup>lt;sup>477</sup> 21 U.S.C. 823(f)(4).

<sup>&</sup>lt;sup>478</sup> Ohio Admin. Code 4731–11–02(D).

<sup>&</sup>lt;sup>479</sup>Ohio Admin. Code 4731–11–02(A) ("A physician shall not utilize a controlled substance other than in accordance with all of the provisions of this chapter of the Administrative Code").

<sup>&</sup>lt;sup>480</sup> Ohio Admin. Code 4731-11-02(D).

<sup>&</sup>lt;sup>481</sup>Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 23, and citations to the record therein.

<sup>&</sup>lt;sup>482</sup> Tr. at 121.

<sup>483</sup> Gov't Ex. Fourteen at 8–9.

records, when instead he prescribed controlled substances as the first course of treatment.

Respondent in his post-hearing brief notes that Dr. Severyn offered no statutory or other authority "which sets forth mandatory requirements for a physical examination and diagnosis." 484 Given the requirement under Ohio law for all physicians to maintain accurate medical records, I find Dr. Zaidi's medical records documenting the visits and treatment of the three undercover officers violated Ohio law.485 Accordingly, this constitutes evidence that Dr. Zaidi's continued DEA registration would be inconsistent with the public interest under Factor Four.486

Respondent also describes at length the attention Dr. Severyn gave to practice requirements that arise after a patient has been receiving pain medication for more than twelve weeks.487 Before I address Respondent's concerns, I note that the foregoing analysis depended not upon regulations cited by Respondent regarding chronic or intractable pain, but instead upon regulations relating to the dispensation of controlled substances generally. Thus, whether Ohio's regulations regarding intractable pain do or do not apply here has no bearing on Dr. Zaidi's failure to respond to red flags, failure to properly diagnose patient conditions, and failure to maintain accurate records. Under Factor Four, the evidence establishes that it would be inconsistent with the public interest to permit Dr. Zaidi to continue to hold a DEA registration, regardless of whether the conditions described in the officers' history of treatment fell within the scope of Ohio's laws concerning the prescription of controlled substances for persons with intractable pain.

Having said that, I note that I do not interpret Dr. Severyn's testimony as having required Dr. Zaidi to conform to the standards for treating intractable pain from the start of the physician/ patient relationship. As Respondent noted in his post-hearing brief, Dr. Severyn acknowledged that the statute and regulation treating chronic pain (Ohio Rev. Code § 4731.052) and intractable pain (Ohio Admin. Code 4731-21-02) do not apply during that phase of treatment where the diagnosis is of acute pain, but apply only after treatment extends past twelve weeks.488 Respondent proposes that the

undercover officers' complaints "were for acute pain and not for 'intractable' or 'chronic' pain" and argues that "[t]he statutes have no application for acute pain." <sup>489</sup> He asserts further that each of the undercover agents "presented with short term, acute pain for which there had been no prior treatment." <sup>490</sup>

Our record reflects, however, that upon making his initial diagnoses in these cases, Dr. Zaidi elected not to characterize the patients' conditions (all of which involved potentially chronic conditions) as either chronic or acute. Instead, he prescribed opioid treatment exclusively, and during the first twelve weeks treated the patients as though their symptoms were not likely to change or improve. At no time during the first twelve weeks of treatment, for example, did Dr. Zaidi indicate he expected to reduce the officers' reliance on narcotics. Thus, from all outward appearances, Dr. Zaidi was treating these patients as though their conditions were not acute, but were instead chronic, from the outset of treatment.

I am mindful that Dr. Zaidi in his post-hearing brief notes that he did not diagnose any of the undercover agents with "chronic" pain; nor, for that matter, did he describe any of the pain as "acute." <sup>491</sup> I am, however, guided by Ohio statutory language that defines "chronic pain" as pain that persists after treatment for longer than three continuous months. <sup>492</sup> As such, by the twelfth week of treatment, Dr. Zaidi's failure to characterize the agents' conditions as chronic is irrelevant.

The distinction regarding chronic or acute designations made by Dr. Severyn, however, did not depend on the patients' condition during the first twelve weeks. My understanding of his testimony is that whether or not a patient is identified as having intractable or chronic pain during the first twelve weeks, the physician must re-assess the patient once the course of treatment enters into its twelfth week. That appears to be what the regulation cited by Respondent calls for. The regulation defines "intractable pain" as "a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found." 493 It also defines "protracted basis" as "a period in excess of twelve continuous

weeks," <sup>494</sup> and articulates a standard of care applicable "[w]hen utilizing any prescription drug for the treatment of intractable pain on a protracted basis or when managing intractable pain with prescription drugs in amounts or combinations that may not be appropriate when treating other medical conditions." <sup>495</sup>

From our record, I found no evidence that Dr. Zaidi regarded as clinically significant the twelve-week benchmark in his treatment of the three undercover agents. His actions during the office visits immediately before and after the twelfth week were remarkable only in that they remained essentially the same—they were cursory, involved no physical examinations, and focused almost entirely on the patients' requests for additional or different narcotics.

What is notable in the treatment of chronic pain in Ohio, however, is that once pain "has persisted after reasonable medical efforts have been made . . . either continuously or episodically, for longer than three continuous months," 496 Ohio law requires pain management physicians to include in their written records a "periodic assessment and documentation of the patient's functional status, including the ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and physical activity of the patient." 497 No such assessment was made, for example, when Officer Leonard appeared on March 21, 2013, either in his interview with Ms. Barrett 498 or during his visit with Dr. Zaidi, twenty-one weeks into treatment.499

As noted in the Government's posthearing brief, Dr. Severyn found that when treatment of the undercover agents extended into the twelfth week, Dr. Zaidi failed to assess the impact of pain on their physical and psychological functions, failed to discuss alternative treatment plans, and failed to document how their pain affected their employment, daily and social activities, and family life. 500 In these respects, the evidence supports, and I find persuasive, Dr. Severyn's opinion that Dr. Zaidi's treatment of the three undercover agents after the twelfth week failed to conform to the applicable

<sup>&</sup>lt;sup>484</sup> Post-Hearing Brief of Respondent at 10.

<sup>&</sup>lt;sup>485</sup> Ohio Admin. Code 4731–11–02(D).

<sup>486 21</sup> U.S.C. 823(f)(4).

<sup>&</sup>lt;sup>487</sup> Post-Hearing Brief of Respondent at 3–12.

<sup>&</sup>lt;sup>488</sup> *Id.* at 4.

<sup>&</sup>lt;sup>489</sup> Id.

<sup>&</sup>lt;sup>490</sup> *Id.* at 5.

<sup>&</sup>lt;sup>491</sup> *Id.* at 9.

<sup>&</sup>lt;sup>492</sup> Ohio Rev. Code § 4731.052(A)(1).

<sup>493</sup> Ohio Admin. Code 4731–21–01(G).

<sup>&</sup>lt;sup>494</sup>Ohio Admin. Code 4731–21–01(L).

<sup>&</sup>lt;sup>495</sup> Ohio Admin. Code 4731–21–02(A).

<sup>&</sup>lt;sup>496</sup> Ohio Rev. Code § 4731.052(A)(1).

<sup>&</sup>lt;sup>497</sup> Ohio Admin. Code 4731–21–02(B)(2).

 $<sup>^{498}</sup>$ Gov't Ex. Ten at 32–33.

<sup>&</sup>lt;sup>499</sup> Gov't Ex. Ten at 33–35.

<sup>&</sup>lt;sup>500</sup> Government's Recommended Findings of Fact, Conclusions of Law[,] and Argument at 24–25.

standard of care and violated Ohio law regarding the treatment of chronic <sup>501</sup> and intractable pain. <sup>502</sup> Therefore, when Dr. Zaidi prescribed controlled substances based on this treatment, he did so without a legitimate medical purpose and outside the usual course of professional practice in Ohio. <sup>503</sup> As such, his prescription practice regarding the three undercover agents during the period after the twelfth week of treatment constitutes an additional basis for finding his continued DEA registration inconsistent with the public interest under Factor Four.

I note the Government also argues that Respondent violated Ohio law by prescribing a controlled substance to his daughter.<sup>504</sup> Ohio regulations state:

Accepted and prevailing standards of care require that a physician maintain detached professional judgment when utilizing controlled substances in the treatment of family members.<sup>505</sup> A physician shall utilize controlled substances when treating a family member only in an emergency situation which shall be documented in the patient's record.<sup>506</sup>

Ohio courts have stated that "utiliz[ing] controlled substances" includes "prescribing" them. 507 Accordingly, if Dr. Zaidi prescribed Vicodin, a Schedule III controlled substance, to his daughter he violated Ohio law. In attempting to prove this allegation, the Government did not, however, present a copy of the prescription Dr. Zaidi allegedly gave to his daughter, nor did it present, as an alterntative, her patient chart. The Government also did not show whether Dr. Zaidi prescribed Vicodin to his daughter in an emergency situation or whether Dr. Zaidi noted the prescription in his daughter's patient chart. The only evidence the Government has offered to support its allegation is the testimony of Diversion Investigator Brinks. Investigator Brinks interviewed Dr. Zaidi "during the search warrants." 508 Apparently, at that time, Dr. Zaidi admitted to Investigator Brinks that "in

the past he had written a prescription for Vicodin to his daughter." <sup>509</sup>

Respondent's counsel pointed out that the evidence does not show whether the prescription was filled. The Wever, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner" while the "corresponding responsibility" for filling the prescription "rests with the pharmacist." Thus, even if a prescription for a controlled substance is not filled, a practitioner may nonetheless violate the Controlled Substances Act by issuing the prescription in the first place.

Respondent's counsel also pointed out, however, that Investigator Brinks did not ask whether the prescription was issued during an emergency. 512 Without that information, or any other evidence to support the Government's allegation, I am unable to conclude that the evidence proves Dr. Zaidi violated Ohio law in issuing a controlled substance prescription to his daughter.

The Government also asserts that Dr. Zaidi violated Ohio law by instituting a practice by which he would pre-sign prescriptions at the beginning of a work day, leaving those prescriptions not needed on that day in storage, so that they could be used the following day; and that he failed to require patient addresses be included in each prescription.513 As the Government correctly points out, federal law provides that "prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient . . . "514 The evidence supports a finding that Dr. Zaidi's office practice included procedures that would permit Kim Maniglia to receive pre-signed but otherwise blank prescriptions from Dr. Zaidi and retain unused scripts for use the next business day.<sup>515</sup> It also supports a finding that Dr. Zaidi did not require controlled substance prescriptions to include a patient's address.516 Each of the prescriptions in our record is for a controlled substance, and none include patient address information.517 Thus, this evidence establishes a violation of federal law relating to controlled substances, and serves as a basis for

making an adverse finding under Factor Four.

The record does not, however, include substantial evidence of an actual instance where Ms. Maniglia had pre-signed prescriptions at the end of a work day, and used the carried-over script the following day for purposes of dispensing controlled substances. Accordingly, this is discussed under Factor Five, but does not serve as a basis for making an adverse finding under Factor Four.

While I do not endorse the Government's assertion that it proved Dr. Zaidi violated Ohio law regarding prescribing to family members, I do find substantial and persuasive evidence establishing that Dr. Zaidi otherwise failed to comply with applicable state and federal laws relating to controlled substances, and that this failure warrants a finding that his continued DEA registration would be inconsistent with the public interest under Factor Four.

#### **Factor Five**

Under Factor Five, after considering the public interest in the context of the first four factors, the Administrator will consider "other conduct which may threaten the public health and safety." 518 Factor Five thus encompasses the universe of conduct not expressly within the scope of the first four factors, but "which creates a probable or possible threat (and not only an actual) threat to public health and safety." 519 Further, agency precedent has generally embraced the principle that any conduct that is properly the subject of Factor Five must have a nexus to controlled substances and the underlying purposes of the Controlled Substances Act. 520

In its post-hearing brief, the Government contends that Respondent "instituted and maintained policies that were contrary to Federal law" in two respects under Factor Five. 521 First, the Government posits that Dr. Zaidi "advised [Kim] Maniglia that including a patient address on a prescription for controlled substances was not necessary" and second, that he "maintained a policy by which employees were forbidden from contacting law enforcement officers in the event they suspected patients were

<sup>&</sup>lt;sup>501</sup> Ohio Rev. Code § 4731.052.

<sup>&</sup>lt;sup>502</sup> Ohio Admin. Code 4731–21–02.

<sup>503 21</sup> CFR 1306.04(a).

 $<sup>^{504}\,\</sup>rm Government's$  Recommended Findings of Fact, Conclusions of Law[,] and Argument at 25.

<sup>505 &</sup>quot;'[F]amily member' means a spouse, parent, child, sibling or other individual in relation to whom a physician's personal or emotional involvement may render that physician unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions." Ohio Admin. Code 4731–11–08.

<sup>&</sup>lt;sup>506</sup> Ohio Admin. Code 4731–11–08(B).

 $<sup>^{507}\,\</sup>mathrm{See}, e.g., Harris\,\mathrm{v.}$  State Med. Bd., 974 NE.2d 207, 216 (Ohio Ct. App. 2012).

<sup>&</sup>lt;sup>508</sup> Tr. at 618.

<sup>&</sup>lt;sup>509</sup> *Id.* at 619.

<sup>&</sup>lt;sup>510</sup> *Id.* at 620.

<sup>511 21</sup> CFR 1306.04(a).

 $<sup>^{512}\,</sup> Tr.$  at 620.

<sup>&</sup>lt;sup>513</sup> Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 25–26.

<sup>&</sup>lt;sup>514</sup> Id. (citing 21 CFR 1306.05(a)).

<sup>&</sup>lt;sup>515</sup> Tr. at 407.

<sup>516</sup> Id. at 429.

<sup>517</sup> Gov't Exs. Fifteen; Eighteen; & 21.

<sup>&</sup>lt;sup>518</sup> 21 U.S.C. 823(f)(5).

<sup>&</sup>lt;sup>519</sup> Roni Dreszer, M.D., 76 FR 19434–01, 19434 n.3 (DEA April 7, 2011).

 $<sup>^{520}</sup>$  Terese, Inc., D/B/A Peach Orchard Drugs, 76 FR 46843–02, 46848 (DEA August 3, 2011).

<sup>&</sup>lt;sup>521</sup>Government's Findings of Fact, Conclusions of Law[,] and Argument at 26.

obtaining multiple prescriptions for controlled substances." 522

As a matter of procedure, I regard the scope of Factor Five to be limited to those portions of our record that do not establish violations of federal law. "Because section 823(f)(5) only implicates 'such other conduct,' it necessarily follows that conduct considered in Factors One through Four may not ordinarily be considered at Factor Five." 523 Thus, if either office policy violates any laws relating to prescribing controlled substances, then it must be considered in the discussion of Factor Four, rather than Factor Five. Failing to put patient addresses on controlled substance prescriptions is a violation of federal law and thus has been addressed in the Factor Four analysis.

I am not, however persuaded that sufficient evidence has been presented to conclude Dr. Zaidi "maintained a policy by which employees were forbidden from contacting law enforcement" <sup>524</sup> when presented with questionable patient conduct. The evidence does tend to establish that Ms. Maniglia felt that laws regarding patient privacy prohibited her from reporting patient activities to law enforcement authorities. <sup>525</sup>

I have carefully reviewed Ms. Maniglia's testimony regarding the reasons she felt constrained in reporting suspicious behavior to law enforcement personnel. Clearly the record indicates that Ms. Maniglia understood patient privacy laws to be very broad in scope. In her understanding of those laws, Ms. Maniglia said, "I ha[ve] been in the field for 20 years and we're not allowed to talk about any patient confidentiality stuff." 526 When asked, however, whether this understanding came from policies instituted by Dr. Zaidi, Ms. Maniglia was clear and consistent in responding in the negative, saying "we never talked about it." 527

Ms. Maniglia's understanding about federal privacy laws as they pertain to pain management clinics is understandable. Federal law in this area is complex and generally tends to restrict disclosure of medical records, as Ms. Maniglia correctly stated. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of Health and Human Services to create standards for

privacy of "individually identifiable health information." <sup>528</sup> In 2001 the Secretary issued the HIPAA Privacy Rule. <sup>529</sup> The rule preempts most state laws affecting medical records to the extent that state laws contradict the Privacy Rule and are less stringent. <sup>530</sup> Under the Rule, a covered entity <sup>531</sup> may not use or disclose protected health information without written authorization from the individual or, alternatively, the opportunity for the individual to agree or object. <sup>532</sup>

However, there are situations in which the covered entity may use or disclose protected health information without the individual's authorization or agreement. These are situations where the entity is obligated by law to disclose information, where the information is requested as part of a judicial or administrative proceeding, or where the information is needed for public health or safety purposes.<sup>533</sup> For example, covered entities may disclose protected health information to health oversight agencies, public health authorities, and to courts or tribunals engaged in judicial or administrative proceedings under circumstances designed to insure that the information is disclosed only to those who need to know.534

There are also several circumstances under which covered entities may disclose protected health information to law enforcement agencies or officials.<sup>535</sup> Protected health information may be disclosed pursuant to laws that require reporting of certain types of injuries or in compliance with a court order, warrant, subpoena (including a grand jury subpoena) summons, or administrative request.<sup>536</sup>

Assuming, as I do, that Ms. Maniglia's testimony is accurate, I think a strong argument can be made for the proposition that Dr. Zaidi's failure to correctly understand the lawenforcement exceptions to HIPAA and to discuss with his staff the role law enforcement plays in preventing abuse and diversion is important. If pain management staff members observe evidence of doctor shopping or diversion of prescribed narcotics, those staff members should be familiar with steps they can and must take to alert the relevant authorities of possible illicit action. Dr. Zaidi is responsible for ensuring that his staff understands the practitioner's role in preventing abuse and diversion of controlled substances. The evidence tends to demonstrate Dr. Zaidi failed to meet this responsibility in the management of his medical practice.

To some extent, therefore, there is evidence that Dr. Zaidi's management of his staff was materially deficient and was inconsistent with the public interest.

I cannot, however, agree with the Government's assertion that the evidence establishes Dr. Zaidi "maintained a policy by which employees were forbidden from contacting law enforcement in the event they suspected patients were obtaining multiple prescriptions for controlled substances from multiple doctors." 537 I found Ms. Maniglia's testimony credible throughout, including when she told me she never talked with Dr. Zaidi about limits on disclosing confidential information.<sup>538</sup> I further found credible her explanation that when she was interviewed by the DEA during the execution of the warrant allowing the search of Dr. Zaidi's office, she was misunderstood. She denied telling the interviewing officer that employees who discovered evidence of doctor shopping were not allowed to report that to law enforcement, explaining, "He misunderstood me. I told him that was [] HIPAA, that we weren't allowed to discuss anything. . . . We were not allowed to call. It was patient confidentiality." 539

<sup>&</sup>lt;sup>522</sup> Id.

<sup>&</sup>lt;sup>523</sup> Joe W. Morgan, D.O., 78 FR 61961-01, 61977 (DEA October 8, 2013).

<sup>&</sup>lt;sup>524</sup> Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 26.

<sup>&</sup>lt;sup>525</sup> Tr. at 411.

<sup>526</sup> Id. at 412.

<sup>527</sup> Id.

<sup>528</sup> Health Insurance Portability and Accountability Act, Pub. L. 104–191, § 264, 110 Stat 1936 (1996).

<sup>&</sup>lt;sup>529</sup> See 45 CFR parts 160 and 164.

The term "individually identifiable health information" means any information, including demographic information collected from an individual, that—

<sup>(</sup>A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

<sup>(</sup>B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and—

<sup>(</sup>i) identifies the individual; or

<sup>(</sup>ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual. 42 U.S.C. 1320d.

<sup>530 45</sup> CFR 160.203-.204.

<sup>&</sup>lt;sup>531</sup> A covered entity is: "(1) A health plan. (2) A health care clearinghouse. (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter." 45 CFR 160.103; see also 45 CFR 164.104. The third category tends to include most healthcare providers since the regulation lists twelve common activities that would subject healthcare providers to HIPAA's requirements. See 45 CFR 160.103.

<sup>&</sup>lt;sup>532</sup> 45 CFR 164.508, 164.510.

<sup>533 45</sup> CFR 164.512.

<sup>&</sup>lt;sup>534</sup> *Id*.

<sup>535</sup> *Id*.

<sup>&</sup>lt;sup>536</sup> Id.

 $<sup>^{537}</sup>$  Government's Proposed Findings of Fact, Conclusions of Law[,] and Argument at 26.

<sup>&</sup>lt;sup>538</sup> Tr. at 412.

<sup>539</sup> *Id.* at 411.

Accordingly, while I find insufficient evidence establishing that Dr. Zaidi established a policy prohibiting his staff from reporting evidence of diversion or abuse, I find his office practice generally created a risk to the public safety in failing to properly train his staff regarding the role of law enforcement officers in detecting abuse and diversion of controlled substances. In this respect, the Government has met its burden of demonstrating that Dr. Zaidi's continued DEA registration would be inconsistent with the public interest under Factor Five.

#### **Evidence of Respondent's Remediation**

Once the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must "present[] sufficient mitigating evidence to assure the Administrator that [the registrant] can be entrusted with the responsibility carried by such a registration." 540 In addition, because "past performance is the best predictor of future performance," 541 the Administrator repeatedly has held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct.542 Further, "admitting fault" is "properly consider[ed]" by DEA to be an important factor in the public interest determination.543 The Administrator repeatedly has held that the "registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." 544 "Once the [G]overnment establishes a prima facie case showing a practitioner has committed acts which render his registration inconsistent with the public interest, the burden shifts to the practitioner to show why his continued registration would be consistent with the public interest." 545

Here the Administrator must proceed without testimony from Dr. Zaidi, and

without evidence of remediation or of an admission of fault. I cannot concur with Respondent's claim that "there is no evidence to suggest that Dr. Zaidi is a threat to the public interest." 546 Evidence that Dr. Zaidi persistently misrepresented the extent of his examination of the three undercover agents is but one example of conduct that threatens the public interest. With respect to remediation, Respondent asserted in his post-hearing brief that "[t]hrough his counsel during the hearing in this matter, there is an acknowledgment of areas Dr. Zaidi could improve. He would take appropriate corrective action to eliminate those errors." 547 I cannot find from this representation any substantial evidence of either contrition or remediation. Accordingly, the Government's prima facie case is established, and the matter is presented to the Administrator without evidence that would compel any outcome other than the revocation of Dr. Zaidi's DEA registration.

#### **Findings of Fact**

1. On October 8, 2013, the Deputy Administrator for the Drug Enforcement Administration issued an order to show cause why the DEA should not revoke its Certificate of Registration BA3842259 issued to Syed Jawed Akhtar-Zaidi, M.D., and should not deny any application for renewal or modification of the same. That certificate authorizes the distribution of controlled substances out of an office located at 34055 Solon Road, Suite 201, Solon, Ohio 44139. The order also immediately suspended this DEA registration, under the authority found in 21 CFR 1301.36(e) and 1301.37(c). By its own terms, Respondent's DEA registration will expire on June 30, 2014.

2. Between September 11, 2012, and May 17, 2013, Respondent prescribed controlled substances to three undercover agents posing as patients. The dates these prescriptions were written; the name, dosage, and quantity of the controlled substances prescribed; and the identity of the agents who received these prescriptions are accurately set forth in paragraphs 2a through 2c in the order to show cause, <sup>548</sup> and are incorporated by reference into this finding.

3. In each of the prescriptions for controlled substances Respondent issued to these agents identified in Finding of Fact Two, Respondent failed to include the patient's address.

4. In the cases of Agent Parkison and Detective Leonard, Respondent based his prescription for controlled substances on a diagnosis of lumbar radiculitis, under conditions where the patients' examination and history did not support such a diagnosis.

5. In the case of Agent Moses, Respondent based his prescription for controlled substances in part on diagnoses of limb pain, leg pain, and osteoarthritis, under conditions where the patient's examination and history did not support such diagnoses.

6. After his initial examination of each undercover officer, Respondent never performed physical examinations in subsequent office visits with these patients, but nonetheless either maintained or increased narcotic prescriptions throughout the course of treatment, generally based on no objective medical findings but instead based on requests by the undercover officers

7. In the case of each undercover officer, Respondent failed to complete and maintain accurate medical records reflecting his examination of these patients in that he reported exaggerated levels of pain; reported completing examinations that were never performed; falsely stated he had examined the patients to detect pupil response to light, range of motion in the upper or lower extremities, chest and heart sounds, abdominal tenderness, and sensory and motor functions; and based his prescriptions for controlled substances on these false examination reports.

8. In the case of each undercover officer, Respondent treated for pain for a period exceeding twelve weeks, but failed either before or after the twelfth week to indicate in the patient's medical chart a diagnosis of chronic pain (including signs, symptoms, and causes); failed to develop a comprehensive assessment of the patient a description of the patient's response to treatment; failed to fully document his periodic assessment and documentation of the patient's functional status, including the ability to engage in work or other purposeful activities, the interference with activities of daily living, quality of family life and social activities; failed to fully document his periodic assessment and documentation of the patient's progress toward treatment objectives, including the intended role of controlled substances within the overall plan of treatment; and failed to fully document that he had addressed with the patient the risks associated with protracted treatment with controlled substances, including informing the

<sup>540</sup> Medicine Shoppe—Jonesborough, 73 FR 364—01, 387 (DEA January 2, 2008) (quoting Samuel S. Jackson, D.D.S., 72 FR 23848, 23853 (DEA May 1, 2007) (quoting Leo R. Miller, M.D., 53 FR 21931, 21932 (DEA June 10, 1988)).

 $<sup>^{541}\,</sup>ALRA\,Labs,\,Inc.,\,v.\,DEA,\,54$  F.3d 450, 452 (7th Cir. 1995).

 <sup>&</sup>lt;sup>542</sup> See Jackson, 72 FR at 23853; John H. Kennedy,
 M.D., 71 FR 35705–01, 35709 (DEA June 21, 2006);
 Prince George Daniels, D.D.S., 60 FR 62884–01,
 62887 (DEA December 7, 1995).

 $<sup>^{543}</sup>$  Hoxie v.  $DEA,\,419$  F.3d 477, 483 (6th Cir. 2005).

<sup>&</sup>lt;sup>544</sup> *Medicine Shoppe—Jonesborough,* 73 FR at 387.

<sup>545</sup> MacKay v. DEA, 664 F.3d 808, 817 (10th Cir. 2010) (citing Medicine Shoppe—Jonesborough, 73 FR at 387).

 $<sup>^{546}\,</sup> Post\text{-Hearing Brief}$  of Respondent at 19.

<sup>&</sup>lt;sup>547</sup> *Id*.

<sup>548</sup> ALJ Ex. One.

patient of the potential for dependence, tolerance, and addiction, and the clinical or monitoring tools the physician may use if signs of addiction, drug abuse, or drug diversion are present.

- 9. In the course of treating each of the undercover officers, Respondent failed to identify in his medical chart and resolve red flags indicating possible controlled substance abuse or diversion, including solicitation by the patient of specific narcotics by name as an initial course of treatment, particularly where the named drugs were OxyContin, Percocet, or Opana, all of which are recognized as frequently diverted narcotics; solicitation by the patient of increasing amounts of narcotic medication or changes in name-brand narcotics without objective medical reasons justifying the change; a patient presenting to the medical office without a government-issued identity card that included the patient's current address; a patient's use of medication provided by non-authorized sources such as a family member; and persistent patient noncompliance with orders for MRIbased studies and refusal to consider non-narcotic treatments including cortisone injections.
- 10. Contemporaneous to the execution of a search warrant of Respondent's premises, Respondent told DEA agents he had prescribed Vicodin to his daughter. There is, however, no copy of the prescription nor any evidence that would permit a determination of the circumstances under which this controlled substance was prescribed, including whether such treatment was provided in an emergency situation.
- 11. Included in Respondent's prescription practice was a protocol by which he would pre-sign prescriptions, many of which were used to prescribe controlled substances. The supply of pre-signed prescriptions would not always be exhausted at the end of the day, and remaining prescriptions would be used the following day. There is, however, insufficient evidence permitting a finding that any left-over prescriptions were used for prescribing controlled substances on a day other than the day the prescription was issued.
- 12. Respondent was the physician in charge of and the only authorized prescribing source at his pain management clinic. In training his clinical staff, Respondent did not require those who assisted in filling out controlled substance prescriptions to include patient addresses on the prescription. Further, he did not provide training to his staff regarding exceptions to patient privacy laws that

apply when the staff members observe behavior relating to controlled substance abuse, misuse, or diversion.

13. Respondent has not provided substantial evidence that he has acknowledged any noncompliance with controlled substance laws, nor that he has undertaken efforts to avoid such noncompliance in the future.

#### **Conclusions of Law**

- 1. When it proposes to revoke a DEA Certificate of Registration or deny any pending applications for such registration, the Government is required to establish by at least a preponderance of the evidence that the holder's continued registration is inconsistent with the public interest.
- 2. Five factors must be considered when determining the public interest in this case:
- (1) The recommendation of the appropriate state licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable state, federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.<sup>549</sup>

- 3. Under 21 U.S.C. 823(f)(1) (Factor One), as is the case here, where the record is silent with respect to the recommendation of the appropriate state licensing board or professional disciplinary authority, Factor One neither supports nor contradicts a finding that Respondent's continued DEA registration is inconsistent with the public interest.
- 4. In order to establish a basis for revoking a Certificate of Registration based on the provisions of 21 U.S.C. 823(f)(2) (Factor Two), and assuming Factor Two applies to Respondent, the Government must present preponderant evidence establishing that the experience of Respondent in dispensing controlled substances is of such character and quality that his continued registration is inconsistent with the public interest. Upon the determinations appearing in Finding of Fact Number Nine (above), where a preponderance of the evidence establishes that Respondent demonstrated a material lack of insight and experience regarding a prescribing source's responsibilities to resolve red flags when prescribing controlled

substances for persons presenting with symptoms of chronic pain, the Government has met its burden of proving Respondent's continued DEA registration would be inconsistent with the public interest under Factor Two, warranting the revocation of that registration and the denial of any pending application for registration.

5. In order to establish a basis for revoking a Certificate of Registration based on the provisions of 21 U.S.C. 823(f)(3) (Factor Three), and assuming Factor Three applies to Respondent, the Government must present evidence of Respondent's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances. As this Factor is neither alleged by the Government nor suggested by the evidence, this Factor may not be considered to support the revocation of Respondent's current DEA registration or deny any pending application for registration.

6. Under 21 U.S.C. 823(f)(4) (Factor Four), the Administrator is to consider the Respondent's compliance with applicable state, federal, or local laws relating to controlled substances.

- 7. Federal law relating to controlled substances includes the requirement that prescriptions for controlled substances include the patient's address.  $^{550}$  Where the  $\bar{\text{G}}$ overnment establishes by at least a preponderance of the evidence, as is the case here, that Respondent issued prescriptions for controlled substances that did not include any patient address information, the Government has met its burden of establishing Respondent's noncompliance with applicable federal law relating to controlled substances, and thereby has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Four.
- 8. Federal law relating to controlled substances include the requirement that all prescriptions for controlled substances must be for a legitimate medical purpose and must be issued in the ordinary course of a professional medical practice. <sup>551</sup> Ohio law includes the requirement that prescriptions for controlled substances must be for legal and legitimate therapeutic purposes. <sup>552</sup> A preponderance of the evidence establishes that Respondent issued controlled substance prescriptions for the three undercover agents described

<sup>&</sup>lt;sup>550</sup> 21 CFR 1306.05(a).

<sup>&</sup>lt;sup>551</sup> Sun & Lake Pharmacy, 76 FR 24523–02, 24530 (DEA May 2, 2011) (quoting 21 CFR 1306.04(a)); George C. Aycock, M.D., 74 FR 17529–01, 17541 (DEA April 15, 2009).

<sup>552</sup> Ohio Rev. Code § 4731.22(B)(3).

herein without first resolving red flags identified in Finding of Fact Nine (above), in a manner that was not in the ordinary course of professional medical practice and not for legitimate therapeutic purposes. A preponderance of the evidence further establishes that Respondent issued controlled substance prescriptions based on diagnoses of radiculitis (with respect to Agent Parkison and Detective Leonard) and limb pain (with respect to Agent Moses) where the objective findings taken together with the examinations and histories obtained by Respondent do not support such diagnoses. Upon such evidence, the Government has met its burden of establishing these prescriptions were not for a legitimate medical or therapeutic purpose and were not written in the ordinary course of Respondent's professional practice, and has established Respondent's noncompliance with applicable federal and state law relating to controlled substances. Accordingly, the Government has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Four.

9. Ohio law includes the requirement that when prescribing controlled substances for pain, the prescribing source "shall complete and maintain accurate medical records reflecting the physician's examination, evaluation, and treatment of all the physician's patients." 553 A preponderance of the evidence establishes that when Respondent issued controlled substance prescriptions for the three undercover agents described herein, he did so based on records that falsely reported the extent and nature of his examination of the patients and falsely reported the patients' reports of pain, as enumerated in Finding of Fact Seven (above). Upon such evidence, the Government has met its burden of establishing Respondent's noncompliance with applicable state law relating to controlled substances, and thereby has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Four.

10. Ohio law defines "chronic pain" as pain that "has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months." <sup>554</sup> A preponderance of the evidence establishes that each of the three

undercover officers presented before Respondent with symptoms of chronic pain. In these cases, Ohio law requires the physician to include in the patient's medical charts a written diagnosis of chronic pain; a plan of treatment that includes documentation that other medically reasonable treatments for relief of the pain have been offered or attempted without adequate or reasonable success; periodic assessments and documentation of the patient's functional status, including the ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities and the patient's physical activities; and periodic documentation of progress towards treatment objectives.<sup>555</sup> Where a preponderance of the evidence establishes that Respondent failed to comply with the requirements of Ohio law applicable to the treatment of chronic pain, on the facts set forth in Finding of Fact Eight (above), the Government has met its burden of establishing Respondent's noncompliance with applicable state law relating to controlled substances, and thereby has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Four.

11. Ohio law provides that "intractable pain" is "pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found." 556 It further provides that specific practice standards apply when utilizing any prescription drug for the treatment of intractable pain on a protracted basis, defining "protracted basis" as a period in excess of twelve continuous weeks.557 Where, as here, the evidence establishes by at least a preponderance that Respondent treated each of the three undercover agents as though there were no cure possible for periods exceeding twelve weeks, Ohio law required that he conform to those practice standards applicable in the treatment of intractable pain. Those standards applicable at the initial evaluation include reporting the patient's complete medical, pain, alcohol and substance abuse histories; an assessment of the impact of pain on the patient's physical and psychological

functions; a review of previous diagnostic studies and previously utilized therapies; an assessment of coexisting illnesses, diseases, or conditions; and an appropriate physical examination.558 Those standards also more generally require a medical diagnosis documented in the patient's medical record that indicates not only the presence of intractable pain but also the signs, symptoms, and causes and, if determinable, the nature of the underlying disease and pain mechanism; and an individualized treatment plan formulated and documented in the patient's medical record specifying the medical justification of the treatment of intractable pain by utilizing prescription drugs, the intended role of prescription drug therapy within the overall plan, and, when applicable, documentation that other medically reasonable treatments for relief of the patient's intractable pain have been offered or attempted without adequate or reasonable success.559 Where a preponderance of the evidence establishes that Respondent failed to comply with the requirements of Ohio law for the treatment of intractable pain, as set forth in Finding of Fact Eight (above), the Government has met its burden of establishing Respondent's noncompliance with applicable state law relating to controlled substances, and thereby has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Four.

12. Ohio law permits a physician to utilize controlled substances when treating a family member only in an emergency situation, and requires the emergency situation to be documented in the patient's medical record. 560 While there is some evidence in our record indicating Respondent prescribed a controlled substance for his daughter, the record does not include the patient's medical record, the prescription, nor sufficient circumstantial facts that would warrant concluding that Respondent violated Ohio law regarding prescribing controlled substances to family members.

13. Under 21 U.S.C. 823(f)(5) (Factor Five), the Administrator is to consider, "Such other conduct which may threaten the public health and safety." Respondent's actions or omissions that threaten the public interest may constitute a basis for revoking a DEA registration under Factor Five, where

<sup>&</sup>lt;sup>553</sup> Ohio Admin. Code 4731–11–02(D).

<sup>554</sup> Ohio Rev. Code § 4731.052(A)(1).

<sup>&</sup>lt;sup>555</sup> Ohio Rev. Code § 4731.052(D).

 $<sup>^{556}\,\</sup>mathrm{Ohio}$  Admin. Code 4731–21–01(G).

 $<sup>^{557}</sup>$  Ohio Admin. Code 4731–21–01(L); Ohio Admin. Code 4731–21–02.

<sup>558</sup> Ohio Admin. Code 4731-21-01(A)(1).

<sup>&</sup>lt;sup>559</sup>Ohio Admin. Code 4731-21-02(A)(2)-(3).

<sup>560</sup> Ohio Admin. Code 4731-11-08(B).

the conduct is not within the scope of Factors One through Four. <sup>561</sup> Where by at least a preponderance of the evidence the Government establishes, as is the case here, that Respondent failed to provide training to his staff regarding exceptions to patient privacy laws that apply when staff members observe behavior relating to controlled substance abuse, misuse, or diversion, the Government has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Five.

14. Federal law requires prescriptions for controlled substances be signed on the date the prescription is issued. 562 Under this law, an office practice in which Respondent signed but otherwise left incomplete scripts in such quantity as to make it possible for incomplete signed scripts to be used on a later day creates the potential for violating federal law. Without more, however, particularly without evidence corroborating Ms. Maniglia's testimony that left-over scripts may have been

used for controlled substance prescriptions on days other than the date signed, there is insufficient evidence to establish a violation of this law. While such evidence does not establish a violation of law so as to fall within the scope of Factor Four, it does demonstrate an office practice that constitutes a threat to the public interest. Accordingly, by this evidence the Government has met its burden of demonstrating that Respondent's continued DEA registration would be inconsistent with the public interest under Factor Five.

15. When responding to the Government's prima facie case establishing cause to find Respondent's continued DEA registration inconsistent with the public interest, Respondent has the opportunity to demonstrate that he recognizes any noncompliance with controlled substance laws and has taken steps to ensure against future noncompliance.<sup>563</sup> Where Respondent

has not provided substantial evidence that he has acknowledged any noncompliance with controlled substance laws, nor that he has undertaken efforts to avoid such noncompliance in the future, Respondent has failed to rebut the Government's prima facie case.

#### Recommendation

As the Government has established its prima facie case by at least a preponderance of the evidence that Respondent's continued DEA registration would be inconsistent with the public interest, and as Respondent has failed to rebut that case through a demonstration of sufficient remediation, Respondent's DEA Certificate of Registration should be REVOKED and any pending application for the renewal or modification of the same should be DENIED.

Dated: February 10, 2014. Christopher B. Mcneil Administrative Law Judge

[FR Doc. 2015–17719 Filed 7–17–15; 8:45 am]

BILLING CODE 4410-09-P

<sup>561 21</sup> U.S.C. 823(f)(5).

<sup>&</sup>lt;sup>562</sup> 21 CFR 1306.05(a).

<sup>563</sup> Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); see also Morall v. DEA, 412 F.3d 165, 173—74 (D.C. Cir. 2005); MacKay v. DEA, 664 F.3d 808, 817 (10th Cir. 2010) (citing Medicine Shoppe—Jonesborough, 73 FRFR 364–01, 387 (DEA January 2. 2008)).



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## Part IV

# The President

Memorandum of June 19, 2015—Delegation of Authority Pursuant to Section 8 of the United States-Israel Strategic Partnership Act of 2014 Memorandum of June 25, 2015—Delegation of Authority To Transfer Certain Funds in Accordance With Section 610 of the Foreign Assistance Act of 1961

Executive Order 13700—Establishing an Emergency Board To Investigate Disputes Between New Jersey Transit Rail and Certain of Its Employees Represented by Certain Labor Organizations

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# **Presidential Documents**

Title 3—

Memorandum of June 19, 2015

The President

Delegation of Authority Pursuant to Section 8 of the United States-Israel Strategic Partnership Act of 2014

Memorandum for the Secretary of State [and] the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate the reporting requirement conferred upon the President by section 8 of the United States-Israel Strategic Partnership Act of 2014 (Public Law 113–296) to the Secretary of State. In carrying out the functions under this delegation, the Secretary of State shall consult with the Secretary of Defense and, as appropriate, other departments and agencies.

The Secretary of State is authorized and directed to publish this memorandum in the Federal Register.

Such

THE WHITE HOUSE, Washington, June 19, 2015

[FR Doc. 2015–17922 Filed 7–17–15; 11:15 am] Billing code 4710–10

## **Presidential Documents**

Memorandum of June 25, 2015

Delegation of Authority To Transfer Certain Funds in Accordance With Section 610 of the Foreign Assistance Act of 1961

#### Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 610 of the Foreign Assistance Act of 1961 (FAA) and section 301 of title 3, United States Code, I hereby delegate to you the authority, subject to fulfilling the requirements of section 652 of the FAA and section 7009(d) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2014 (Division K, Public Law 113–76), and corresponding provisions of prior acts for Fiscal Years 2010–2012, to make the determination necessary for and to execute the transfer of \$12,468,000 of Fiscal Year (FY) 2010 International Narcotics and Law Enforcement (INCLE) funds to the Economic Support Fund (ESF) account; \$13,000,000 of FY 2011 INCLE funds to the ESF account; \$2,032,000 of FY 2014 INCLE-Overseas Contingency Operations (OCO) funds to the ESF–OCO account; and \$39,300,000 in FY 2014 Foreign Military Financing–OCO funds to the ESF–OCO account.

You are authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE, Washington, June 25, 2015

[FR Doc. 2015–17925 Filed 7–17–15; 11:15 am] Billing code 4710–10

## **Presidential Documents**

Executive Order 13700 of July 15, 2015

Establishing an Emergency Board To Investigate Disputes Between New Jersey Transit Rail and Certain of Its Employees Represented by Certain Labor Organizations

Disputes exist between New Jersey Transit Rail and certain of its employees represented by certain labor organizations. The labor organizations involved in these disputes are designated on the attached list, which is made part of this order.

The disputes have not heretofore been adjusted under the provisions of the Railway Labor Act, as amended, 45 U.S.C. 151–188 (RLA).

A party empowered by the RLA has requested that the President establish an emergency board pursuant to section 9A of the RLA (45 U.S.C. 159a).

Section 9A(c) of the RLA provides that the President, upon such request, shall appoint an emergency board to investigate and report on the disputes.

NOW, THEREFORE, by the authority vested in me as President by the Constitution and the laws of the United States, including section 9A of the RLA, it is hereby ordered as follows:

**Section 1.** Establishment of Emergency Board (Board). There is established, effective 12:01 a.m. eastern daylight time on July 16, 2015, a Board of three members to be appointed by the President to investigate and report on these disputes. No member shall be pecuniarily or otherwise interested in any organization of employees or any carrier. The Board shall perform its functions subject to the availability of funds.

**Sec. 2.** *Report.* The Board shall report to the President with respect to the disputes within 30 days of its creation.

**Sec. 3.** Maintaining Conditions. As provided by section 9A(c) of the RLA, for 120 days from the date of the creation of the Board, no change in the conditions out of which the disputes arose shall be made by the parties to the controversy, except by agreement of the parties.

**Sec. 4.** Records Maintenance. The records and files of the Board are records of the Office of the President and upon the Board's termination shall be maintained in the physical custody of the National Mediation Board.

**Sec. 5.** Expiration. The Board shall terminate upon the submission of the report provided for in section 2 of this order.

Such

THE WHITE HOUSE, July 15, 2015.

Billing code 3295–F5–P

#### LABOR ORGANIZATIONS

International Brotherhood of Electrical Workers
Transportation Communications International Union/IAM
Brotherhood of Locomotive Engineers and Trainmen
International Association of Sheet Metal, Air, Rail and
Transportation Workers - Transportation Division (UTU)
International Association of Machinists & Aerospace Workers
Brotherhood of Railroad Signalmen
National Conference of Firemen & Oilers, SEIU
International Association of Sheet Metal, Air, Rail and
Transportation Workers
American Train Dispatchers Association
Brotherhood of Maintenance of Way Employes Division
International Brotherhood of Boilermakers
Transport Workers Union of America

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