Agricultural Marketing Service

RULES
Changing of Container Requirements:
  Oranges and Grapefruit Grown in Lower Rio Grande Valley in Texas, 52944–52946

Electronic Mailing of Notice of Hearing:
  General Regulations for Federal Fruit, Vegetable, and Specialty Crop Marketing Agreements and Orders, 52943–52944

Marketing Orders:
  Hazelnuts Grown in Oregon and Washington, 52946–52950

PROPOSED RULES
Change in Grade and Size Requirements:
  Oranges, Grapefruit, Tangerines, and Pummelos Grown in Florida and Imported Grapefruit, 53003–53007

Agriculture Department
See Agricultural Marketing Service
See Rural Utilities Service

Antitrust Division
NOTICES
Changes under the National Cooperative Research and Production Act:
  Consortium for Execution of Rendezvous and Servicing Operations, 53106

Census Bureau
NOTICES
Suspension of the Geographically Updated Population Certification Program for Places Incorporating or Annexing Between Censuses, 53029

Chemical Safety and Hazard Investigation Board
NOTICES
Meetings; Sunshine Act, 53027–53028

Civil Rights Commission
NOTICES
Meetings:
  West Virginia Advisory Committee, 53028–53029
  Meetings; Sunshine Act, 53028

Coast Guard
RULES
Drawbridge Operations:
  Sacramento River, Sacramento, CA, 52976
  Willamette River at Portland, OR, 52976–52977

Safety Zones:
  Delaware River, Penn’s Landing, Philadelphia, PA, Fireworks Display, 52977–52979
  Fox River, Brown County Fireworks, Green Bay, WI, 52981–52983
  Hornblower Fireworks Display; San Francisco Bay; San Francisco, CA, 52979–52981

PROPOSED RULES
Safety Zones:
  NASA Activities, Gulf of Mexico, Galveston, TX, 53023–53026

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53071–53072

Certificates of Alternative Compliance:
  Blount Boats Inc., Hull TGI–329, 53072

Meetings:
  National Maritime Security Advisory Committee, 53070–53071

Commerce Department
See Census Bureau
See Industry and Security Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration

Committee for Purchase From People Who Are Blind or Severely Disabled
NOTICES
Procurement List; Additions and Deletions, 53049–53050

Community Living Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Centers for Independent Living Program Performance Report, 53064–53065
  Independent Living Services Program Performance Report, 53062–53063
  State Plan for Independent Living, 53063–53064

Defense Department
PROPOSED RULES
Foreign Criminal and Civil Jurisdiction, 53020–53023

Drug Enforcement Administration
NOTICES
Bulk Manufacturer of Controlled Substances Registration, 53106–53107
Importer of Controlled Substances Application:
  Fisher Clinical Services, Inc., 53108
  Noramco Inc., 53107–53108
Importer of Controlled Substances Registration, 53107

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
  Accrediting Agency, Foreign Medical and Foreign Veterinarian Program Comparability Database Approval, 53050

Energy Department
See Federal Energy Regulatory Commission

Environmental Protection Agency
RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
  Determination of Attainment by the Attainment Date and Clean Data Determination for the Logan, UT-ID 2006
  24-Hour PM2.5 Nonattainment Area, 52983–52986
Pesticide Tolerances:
  Boscalid, 52991–52996
  Prothioconazole, 52986–52991
Tolerance Exemptions:
  Tetrahydrofurfuryl Alcohol, 52996–53002
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Facility Ground-Water Monitoring Requirements, 53060–53061
Fuel Use Requirements for Great Lake Steamships, 53059–53060
Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Georgia, 53059
Environmental Impact Statements: Availability, etc.; Weekly Receipts, 53053–53054
Pesticide Registration Maintenance Fee: Voluntarily Cancel Certain Pesticide Registrations, 53054–53059

Federal Aviation Administration
RULES
Amendment of the Prohibition Against Certain Flights in Specified Areas of the Simferopol and Dnipropetrovsk Flight Information Regions, 52954–52962
NOTICES
Petition for Exemption; Summaries: Anthony Ison, Esq., 53145

Federal Communications Commission
PROPOSED RULES
Petition for Reconsideration of Action in Rulemaking Proceeding; Correction, 53026

Federal Contract Compliance Programs Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Leadership in Equal Access and Diversity Award, 53111–53112

Federal Deposit Insurance Corporation
NOTICES
Terminations of Receivership:
10142, Madisonville State Bank, Madisonville, TX, 53061

Federal Energy Regulatory Commission
NOTICES
Combined Filings, 53050–53053
Environmental Assessments: Availability, etc.; Alpine Pacific Utilities Hydro, LLC, 53052–53053
Initial Market-Based Rate Filings Including Requests for Blanket Section 204 Authorizations:
Luminant Energy Co., LLC, 53052

Federal Highway Administration
NOTICES
Federal Agency Actions:
Transportation Project in Washington State, 53145–53147

Federal Housing Finance Agency
RULES
Responsibilities of Boards of Directors, Corporate Practices, and Corporate Governance, 52950–52954

Federal Maritime Commission
NOTICES
Agreements Filed, 53061–53062

Federal Motor Carrier Safety Administration
NOTICES
Commercial Driver’s License Standards: Exemption Application:
CRST Expedited, 53149–53150
Commercial Driver’s License Standards Exemption Application:
Isuzu North America Corp., 53151–53152
Parts and Accessories Necessary for Safe Operation; Exemption Applications:
Castignoli Enterprises, 53147–53149

Fish and Wildlife Service
NOTICES
Endangered and Threatened Species:
Habitat Conservation Plan and Categorical Exclusion for the Mount Hermon June Beetle, Santa Cruz County, CA, 53080–53081
Incidental Take Permit Application, Habitat Conservation Plan for Sand Skink, Lake County, FL, 53074–53075
Recovery Permit Applications, 53073–53074
Environmental Impact Statements; Availability, etc.; American Electric Power American Burying Beetle Habitat Conservation Plan in Arkansas, Oklahoma, and Texas, 53077–53078
Eastern Collier Property Owners, LLC, Multi-species Habitat Conservation Plan, Collier County, FL, 53078–53080
South Bay Salt Pond Restoration Project, Phase 2; Don Edwards National Wildlife Refuge, CA, 53075–53077

Food and Drug Administration
RULES
Medical Devices:
Anesthesiology Devices; Classification of the Positive Airway Pressure Delivery System, 52964–52966
General and Plastic Surgery Devices; Classification of the Hemostatic Device for Intraluminal Gastrointestinal Use, 52970–52972
General and Plastic Surgery Devices; Classification of the Light Based Energy Source Device for Topical Application, 52968–52970
General and Plastic Surgery Devices; Classification of the Wound Autofluorescence Imaging Device, 52966–52968
Neurological Devices; Classification of the Thermal Vestibular Stimulator for Headache, 52972–52973
Ophthalmic Devices; Classification of the Intranasal Electrostimulation Device for Dry Eye Symptoms, 52973–52975

NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs, 53065–53067
Determinations of Regulatory Review Periods for Purposes of Patent Extensions:
IMFINZI, 53067–53068
New Drug Applications:
Sanofi-Aventis, U.S., LLC, et al.; Withdrawal of Approval, 53068–53069

Health and Human Services Department
See Community Living Administration
See Food and Drug Administration
See National Institutes of Health
Homeland Security Department
See Coast Guard
See U.S. Immigration and Customs Enforcement

Indian Affairs Bureau
NOTICES
Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Data Elements for Student Enrollment in Bureau-funded
Schools, 53081–53082

Industry and Security Bureau
NOTICES
Denial of Export Privileges; 53029–53030

Interior Department
See Fish and Wildlife Service
See Indian Affairs Bureau
See National Park Service
See Ocean Energy Management Bureau

Internal Revenue Service
NOTICES
Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 53152

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders,
or Reviews:
Carbon and Certain Alloy Steel Wire Rod from Mexico,
53030–53032
Subsidy Programs Provided by Countries Exporting
Softwood Lumber and Softwood Lumber Products to
the United States, 53032–53033

International Trade Commission
NOTICES
Investigations; Determinations, Modifications, and Rulings,
etc.:
Certain LTE- and 3G-Compliant Cellular Communications
Devices, 53105–53106

Justice Department
See Antitrust Division
See Drug Enforcement Administration
See Justice Programs Office
NOTICES
Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
2019 School Crime Supplement to the National Crime
Victimization Survey, 53108–53109

Justice Programs Office
NOTICES
Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
2018 Census of Law Enforcement Training Academies,
53109–53110
Survey of State Attorneys General Offices: Human
Trafficking, 53110–53111

Labor Department
See Federal Contract Compliance Programs Office
See Mine Safety and Health Administration

Mine Safety and Health Administration
NOTICES
Petitions for Modification:
Application of Existing Mandatory Safety Standard,
53112–53113

National Aeronautics and Space Administration
NOTICES
Meetings:
Aeronautics Committee, 53113
Human Exploration and Operations Research Advisory
Committee, 53113–53114

National Institutes of Health
NOTICES
Meetings:
National Heart, Lung, and Blood Institute, 53069–53070

National Oceanic and Atmospheric Administration
NOTICES
Endangered and Threatened Species:
Takes of Anadromous Fish, 53048–53049
Environmental Impact Statements; Availability, etc.:
Proposed Monterey Peninsula Water Supply Project,
53033
Takes of Marine Mammals Incidental to Specified
Activities:
US 101/Chehalis River Bridge-Scour Repair in
Washington State, 53033–53048

National Park Service
NOTICES
Inventory Completions:
Department of Anthropology at Indiana University,
Bloomington, IN, 53084–53085
Fowler Museum at the University of California Los
Angeles, Los Angeles, CA, 53085–53086
Fowler Museum at the University of California Los
Angeles, Los Angeles, CA; Correction, 53082–53083,
53086–53087
The Field Museum, Chicago, IL, 53087–53088
Repatriation of Cultural Items:
Fowler Museum at the University of California Los
Angeles, Los Angeles, CA, 53083–53084, 53088–
53089

National Science Foundation
NOTICES
Meetings:
Advisory Committee for Mathematical and Physical
Sciences, 53114
Proposal Review Panel for International Science and
Engineering, 53114–53115
Membership of Senior Executive Service Performance
Review Board, 53114

Nuclear Regulatory Commission
NOTICES
Direct Transfer of Licenses; Applications:
Oyster Creek Nuclear Generating Station; Consideration
of Approval of Transfer of License and Conforming
Amendment, 53119–53122
Environmental Impact Statements; Availability, etc.:
Interim Storage Partners LLC’s Consolidated Interim
Storage Facility, 53115–53116
License Transfers:
Entergy Nuclear Vermont Yankee, LLC, Entergy Nuclear Operations, Inc., NorthStar Vermont Yankee, LLC, NorthStar Nuclear Decommissioning Company, LLC, Vermont Yankee Nuclear Power Station, 53116–53118
Performance Review Boards for Senior Executive Service, 53118–53119

Ocean Energy Management Bureau
NOTICES
Commercial Leasing for Wind Power Development:
Outer Continental Shelf Offshore California, 53096–53104
Commercial Leasing for Wind Power on the Outer Continental Shelf:
Atlantic Wind Lease Sale 4A Offshore Massachusetts, 53089–53096
Environmental Impact Statements; Availability, etc.:
Deepwater Wind South Fork, LLC Proposed Wind Energy Facility Offshore Rhode Island and Massachusetts, 53104–53105

Postal Regulatory Commission
NOTICES
New Postal Products, 53122–53123

Postal Service
NOTICES
Product Changes:
Priority Mail Express and Priority Mail Negotiated Service Agreement, 53123–53124
Priority Mail Negotiated Service Agreement, 53123

Presidential Documents
ADMINISTRATIVE ORDERS
Defense and National Security:

Rural Utilities Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53027

Securities and Exchange Commission
RULES
Regulation Crowdfunding and Regulation A Relief and Assistance for Victims of Hurricane Michael, 52962–52964
PROPOSED RULES
Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital Requirements for Broker-Dealers, 53007–53020
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 53127–53128
Self-Regulatory Organizations; Proposed Rule Changes:
Fixed Income Clearing Corp., 53131–53134
ICE Clear Credit, LLC, 53136–53138
Nasdaq GEMX, LLC, 53134–53136
National Securities Clearing Corp., 53128–53131
The Depository Trust Co., 53138–53141

Small Business Administration
NOTICES
Major Disaster Declarations:
Florida, 53142–53143
Florida; Amendment 2, 53143
Georgia, 53142
North Carolina; Public Assistance Only, 53141–53142

State Department
NOTICES
Culturally Significant Objects Imported for Exhibition:
Mrinalini Mukherjee, 53144
Renaissance Splendor: Catherine de Medici’s Valois Tapestries, 53143–53144
Performance Review Board Members, 53143

Susquehanna River Basin Commission
NOTICES
Projects Approved:
Consumptive Uses of Water, 53144
Projects Rescinded:
Consumptive Uses of Water, 53144–53145

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See Federal Motor Carrier Safety Administration

Treasury Department
See Internal Revenue Service

U.S. Immigration and Customs Enforcement
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Veterans Affairs Department
NOTICES
Meetings:
Advisory Committee on Cemeteries and Memorials, 53152–53153

Separate Parts In This Issue

Part II
Presidential Documents, 53155–53157

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.
To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.
CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

3 CFR
Administrative Orders:
Memorandums:
Memorandum of
   October 16, 2018........53157

7 CFR
900......................................52943
906......................................52944
982......................................52946
Proposed Rules:
905......................................53003
944......................................53003

12 CFR
1239......................................52950
1273......................................52950

14 CFR
91..........................................52954

17 CFR
227......................................52962
230......................................52962
Proposed Rules:
240......................................53007

21 CFR
868......................................52964
876 (3 documents)............52966, 52968, 52970
882......................................52972
886......................................52973

32 CFR
Proposed Rules:
151......................................53020

33 CFR
117 (2 documents)..........52976
165 (3 documents)............52977, 52979, 52981
Proposed Rules:
165......................................53023

40 CFR
52.........................................52983
180 (3 documents)............52986, 52991, 52996

47 CFR
Proposed Rules:
63........................................53026
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.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 900

[Doc. No. AMS–SC–18–0066; SC18–900–2 FR]

General Regulations for Federal Fruit, Vegetable, and Specialty Crop Marketing Agreements and Orders; Electronic Mailing of Notice of Hearing

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule revises the general regulations for Federal fruit, vegetable, and specialty crop marketing agreements and marketing orders (orders) to allow the use of electronic communication as a method for notifying industry and the public of hearings for proceedings related to proposing new or amending existing orders.

DATES: Effective October 19, 2018.

FOR FURTHER INFORMATION CONTACT: Debbie Wray, Senior Marketing Specialist, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 2202 Monterey Street, Suite 102–B, Fresno, CA 93721; Telephone: (559) 487–5901, Fax: (559) 487–5906 or Email: Debbie.Wray@ams.usda.gov or Michelle.Sharrow@ams.usda.gov.

Small businesses may request information on complying with this rule by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: Richard.Lower@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This final rule is issued under the general regulations for Federal marketing agreements and orders (7 CFR part 900), effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.”

The Department of Agriculture (USDA) is issuing this final rule in conformance with Executive Orders 12866, 13563, and 13175. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See the Office of Management and Budget’s (OMB) Memorandum titled, “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled ‘Reducing Regulation and Controlling Regulatory Costs’” (February 2, 2017).

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule authorizes USDA’s Agricultural Marketing Service (AMS) to use either electronic communication or a postal or other delivery service to mail a notice of hearing to industry and the public for proceedings related to proposing new or amending existing orders.

Part 900 provides the procedural requirements that govern proceedings to formulate orders and when necessary, to amend existing orders. These proceedings include holding a public hearing where, among other things, witnesses provide testimony about the proposal and evidence is admitted for consideration by the Secretary of Agriculture.

Section 900.4(b) requires AMS to mail a true copy of a notice of hearing to each of the persons known to the AMS Administrator to be interested in the proceedings. However, the method to be used for mailing the notice is not specified. Historically, AMS has mailed paper copies of the notice using the United States Postal Service or other postal delivery services. These mailings may number in the hundreds, depending on the industry affected by the proposal.

This final rule revises § 900.4 to provide that the mailing of a notice of hearing may be done electronically or by using a postal or other delivery service. By providing that electronic communication may be used for mailing, this action will help strengthen and modernize AMS’s outreach process and will reduce costs associated with paper mailings. Eventually, if all notice recipients have access to electronic communication as a delivery method and have adapted to its use, the older, more costly paper delivery methods could be eliminated.

Administrative Procedure Act and Regulatory Flexibility Act

This final rule revises agency rules of practice and procedure. Under the Administrative Procedure Act, prior notice and opportunity for comment are not required for the revision of agency rules of practice and procedure. 5 U.S.C. 553(b)(3)(A). Only substantive rules require publication 30 days prior to their effective date. 5 U.S.C. 553(d). Therefore, this final rule is effective upon publication in the Federal Register.

In addition, because prior notice and opportunity for comment are not required to be provided for this final rule, this rule is exempt from the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq.

Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

AMS is committed to complying with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen
access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: http://www.ams.usda.gov/rules-regulations/moa/small-businesses. Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the FOR FURTHER INFORMATION CONTACT section.

List of Subjects in 7 CFR Part 900

Administrative practice and procedure, Freedom of information, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth above, 7 CFR part 900 is amended as follows:

PART 900—GENERAL REGULATIONS

§ 900.4 Institution of proceeding.

The authority citation for part 900 continues to read as follows:


2. In § 900.4, revise paragraph (b)(1)(ii) to read as follows:

(b)(1)(ii) By mailing a true copy of the notice of hearing, using a postal or other delivery service or electronic communication, to each of the persons known to the Administrator to be interested therein;

SUPPLEMENTARY INFORMATION: This final rule, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This final rule is issued under Marketing Agreement and Order No. 906, as amended (7 CFR part 906), regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas. Part 906 (referred to as the “Order”) is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.” The Texas Valley Citrus Committee (Committee) locally administers the Order and is comprised of growers and handlers of Texas citrus operating within the production area.

The Department of Agriculture (USDA) is issuing this final rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB’s Memorandum titled “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled ‘Reducing Regulation and Controlling Regulatory Costs’” (February 2, 2017).

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This final rule removes five containers from the list of authorized containers under the Order and adds seven new containers to the list. This action also modifies the descriptions of two authorized containers. The Committee recommended these changes to align the Order’s container regulations with current industry practices. The Committee unanimously recommended the changes at a meeting on June 8, 2017.

Section 906.40(d) of the Order authorizes the issuance of regulations to fix the size, weight, capacity, dimensions, or pack of the container or containers which may be used in the packaging, transportation, sale, shipment, or other handling of fruit. Section 906.340 provides that no handler shall handle any variety of oranges or grapefruit grown in the production area unless such fruit is packed in one of the containers specified under the Order. This section also specifies a detailed list of the containers currently authorized under the Order. In addition, this section allows the Committee to approve the use of other types and sizes of containers for testing for research purposes.

The Committee reviewed the containers listed in § 906.340 and compared them to the containers being utilized throughout the industry. This process included surveying handlers to determine which containers were being used. As a result, the Committee determined five of the authorized
containers were no longer being used to pack Texas oranges or grapefruit.

The Committee also reviewed the list of experimental containers that had been approved for testing purposes. Seven of the experimental containers have been widely accepted throughout the Texas citrus industry and are being used to pack and ship Texas citrus. As a result of the review, the Committee voted to remove the five containers that were no longer being used from the list of authorized containers and add the seven experimental containers to § 906.340.

The Committee also discussed that while the description in § 906.340(a)(1)(ii) of the closed fully telescopic fiberboard carton with approximate inside dimensions of 16½ by 10¾ by 9½ inches is correct, this container is commonly known throughout the Texas citrus industry as a standard carton. Consequently, for clarification purposes, the Committee voted to add the words “Standard Carton” to this container description. Further, the Committee noted that in § 906.340(a)(1)(iv) poly or mesh bags can be used to pack oranges and grapefruit to a capacity of 5, 8, 10, or 18 pounds of fruit, but that only oranges can be packed in the 4-pound bags. During the discussion, Committee members agreed handlers should also be allowed to ship grapefruit in 4-pound bags. Thus, the Committee voted to update the description to allow for the packing of both oranges and grapefruit in poly or mesh bags having a capacity of 4 pounds.

These changes reflect the containers being utilized throughout the industry and aligns the regulations with current industry practices.

Section 8e of the Act provides that when certain domestically produced commodities, including oranges, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. As this rule changes the container requirements under the domestic handling regulations, no corresponding change to the import regulations is required.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionally burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 170 producers of oranges and grapefruit in the production area and 13 handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

Based on National Agricultural Statistics Service (NASS) and Committee data, the average price for Texas citrus during the 2016–17 season was approximately $16 per carton, and total shipments were 7.6 million cartons. Using the average price and shipment information, the number of handlers (13), and assuming a normal distribution, the majority of handlers would have average annual receipts of $9.4 million, which is greater than $7,500,000. ($16 per carton times 7.6 million cartons equals $121.6 million, divided by 13 equals $9.4 million per handler.) Thus, the majority of Texas citrus handlers may be classified as large business entities.

In addition, based on NASS information, the weighted grower price for Texas citrus during the 2016–17 season was approximately $9.35 per carton. Using the weighted average price and shipment information, the number of producers (170) and assuming a normal distribution, the majority of producers would have annual receipts of $418,000, which is less than $750,000. ($9.35 per carton times 7.6 million cartons equals $71.06 million, divided by 170 equals $418,000 per producer.) Thus, the majority of Texas citrus producers may be classified as small entities.

This final rule revises the container requirements established under the Order. This rule removes five containers from the list of authorized containers and adds seven new containers to the list. This action also updates one container to allow handlers to use it to pack oranges and grapefruit, and modifies the description of another container to indicate it is the standard container used by the industry. These changes align the list of authorized containers with current industry needs and practices. This rule revises § 906.340. Authority for these changes is provided in § 906.40.

It is not anticipated that this final rule will impose additional costs on handlers or growers, regardless of size. The containers removed from the list of authorized containers are no longer being used by the industry. This rule provides an additional container for packing grapefruit, clarifies the description for one container, and adjusts the container regulations to better reflect current industry practices. The benefits of this rule are expected to be equally available to all fresh orange and grapefruit growers and handlers, regardless of size.

The Committee considered alternatives to this action, including making no changes to the list of authorized containers. However, it was determined that making the recommended changes provides an up-to-date list of containers currently being used by the Texas citrus industry. Therefore, the Committee rejected this alternative.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the Order’s information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0189, Fruit Crops. No changes in those requirements are necessary as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This final rule does not impose any additional reporting or recordkeeping requirements on either small or large Texas orange and grapefruit handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes. USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

The Committee’s meeting was widely publicized throughout the Texas citrus industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the June 6, 2017, meeting was a public meeting and all entities, both large and small, were able to express their views on this issue.
A proposed rule concerning this action was published in the Federal Register on July 6, 2018 (83 FR 31471). Copies of the proposed rule were sent via email to all Committee members and Texas citrus handlers. The proposed rule was made available through the internet by USDA and the Office of the Federal Register. A 30-day comment period ending August 6, 2018, was provided to allow interested persons to respond to the proposal. No comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: http://www.ams.usda.gov/rules-regulations/maa/small-businesses. Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the FOR FURTHER INFORMATION CONTACT section.

After consideration of all relevant matter presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared purpose of the Act.

List of Subjects in 7 CFR Part 906

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping.

For the reasons set forth in the preamble, 7 CFR part 906 is amended as follows:

PART 906—ORANGES AND GRAPEFRUIT GROWN IN LOWER RIO GRANDE VALLEY IN TEXAS

1. The authority citation for 7 CFR part 906 continues to read as follows:


2. Revise § 906.340(a)(1) to read as follows:

§ 906.340 Container, pack, and container marking regulations.

(a) * * *

(i) Closed fiberboard carton with approximate inside dimensions of 13 1/4 x 10 1/2 x 7 1/4 inches: Provided, That the container has a Mullen or Cady test of at least 1,100 pounds, and that it is used only once for the shipment of citrus fruit: And Provided further, That the container may be used to pack any poly or mesh bags authorized in this section, or bulk fruit;

(ii) Closed fully telescopic fiberboard carton with approximate inside dimensions of 16 1/2 x 10 x 9 3/4 inches (Standard carton);

(iii) Poly or mesh bags having a capacity of 4, 5, 8, 10, or 18 pounds of fruit;

(iv) Rectangular or octagonal bulk fiberboard crib with approximate dimensions of 46 to 47 1/2 inches in length, 37 to 38 inches in width, and 36 inches in height: Provided, That the container has a Mullen or Cady test of at least 1,300 pounds, and that it is used only once for the shipment of citrus fruit: And Provided further, That the container may be used to pack any poly or mesh bags authorized in this section, or bulk fruit;

(v) Rectangular or octagonal 1/2 fiberboard crib with approximate dimensions of 46 to 47 1/2 inches in length, 37 to 38 inches in width, and 26 to 26 1/2 inches in height: Provided, That the crib has a Mullen or Cady test of at least 1,300 pounds, and that it is used only once for the shipment of citrus fruit: And Provided further, That the container may be used to pack any poly or mesh bags authorized in this section, or bulk fruit;

(vi) Octagonal fiberboard crib with approximate dimensions of 46 to 47 1/2 inches in length, 37 to 38 inches in width, and 25 inches in height: Provided, That the crib has a Mullen or Cady test of at least 1,300 pounds, and that it is used only once for the shipment of citrus fruit: And Provided further, That the crib may be used to pack any poly or mesh bags authorized in this section, or bulk fruit;

(vii) Fiberboard box holding two layers of fruit, with approximate dimensions of 23 inches in length, 15 1/2 inches in width, and 7 inches in depth: Reusable collapsible plastic container with approximate dimensions of 23 inches in length, 15 inches in width, and 7 to 11 inches in depth;

(viii) Reusable collapsible plastic bin with approximate dimensions of 36 1/4 x 44 3/4 x 27 inches;

(x) Octagonal bulk triple wall fiberboard crib with approximate dimensions of 37 3/4 inches in length, 25 inches in width, and 25 inches in height: Provided, That the container has a Mullen or Cady test of at least 1,100 pounds: And Provided further, That the container may be used to pack any poly or mesh bags authorized in this section, or bulk fruit;

(xi) Bag having the capacity of 15 pounds of fruit, either in a combination 1/2 poly and 1/2 mesh bag or mesh bag;

(xii) Reusable collapsible plastic mini bin with approximate dimensions of 39 3/4 inches in length, 24 inches in width, and 30 1/2 inches in height: Provided, That the container may be used to pack any poly or mesh bags authorized in this section, or bulk fruit;

(xiii) Bag having the capacity of three pounds of fruit;

(xiv) Standard carton with approximate inside dimensions of 16.375 x 10.6875 x 10.75 inches;

(xv) % Body master carton with approximate inside dimensions of 19.5385 x 13.125 x 11.625 inches, one piece;

(xvi) Euro % (5 Down) with approximate inside dimensions of 22.813 x 14.688 x 7.936 inches;

(xvii) Fiberboard one piece display container with approximate inside dimensions of 23 inches x 15 inches x 9 1/2 up to 10 1/2 inches in depth;

(xviii) Such types and sizes of containers as may be approved by the committee for testing in connection with a research project conducted by or in cooperation with the committee: Provided, That the handling of each lot of fruit in such test containers shall be subject to prior approval and under the supervision of the committee.

* * * *


Bruce Summers,
Administrator, Agricultural Marketing Service.

[FR Doc. 2018–22759 Filed 10–18–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 982


Hazelnuts Grown in Oregon and Washington: Order Amending Marketing Order No. 982

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends Marketing Order No. 982 (Order), which regulates the handling of hazelnuts grown in Oregon and Washington. The amendments were proposed by the Hazelnut Marketing Board (Board) and add the authority to regulate quality for the purpose of pathogen reduction and to establish different regulations for different markets.

This final rule also makes administrative revisions to subpart headings to bring the language into conformance with the Office of Federal Register requirements.

DATES: This rule is effective November 19, 2018.

FOR FURTHER INFORMATION CONTACT: Melissa Schmaedick, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, Post Office Box 952, Moab, UT 84532; Telephone: (202) 557–4783, Fax: (435) 259–1502; or Michelle Sharrow, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: Melissa.Schmaedick@ams.usda.gov or Michelle.Sharrow@ams.usda.gov.

Small businesses may request information on this proceeding by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: Richard.Lower@ams.usda.gov.


This action is governed by the provisions of sections 556 and 557 of title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Orders 12866, 13563, and 13175. Additionally, because this rule does not meet the definition of a significant regulatory action it does not trigger the requirements contained in Executive Order 13771. See the Office of Management and Budget’s (OMB) Memorandum titled “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017 titled “Reducing Regulation and Controlling Regulatory Costs”” (February 2, 2017).

Notice of this rulemaking action was provided to tribal governments through the Office of Tribal Relations.

Preliminary Statement

This action finalizes an amendment to regulations issued to carry out a marketing order as defined in 7 CFR 900.2. This rule is issued under Marketing Order No. 982, as amended (7 CFR part 982), regulating the handling of hazelnuts grown in Oregon and Washington. Part 982 (referred to as the “Order”) is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.” The final rule was formulated on the record of a public hearing held on October 18, 2016, in Wilsonville, Oregon. The hearing was held pursuant to the provisions of the Act, and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR part 900).

The purpose of pathogen reduction and quality regulations for different markets was approved by at least two-thirds of the growers voting in the referendum, representing at least two-thirds of the volume of hazelnuts produced by those voting. The amendment adding authority to regulate quality was favored by 69.5 percent of the total volume of hazelnuts produced by those voting. The amendment adding authority to establish different regulations for different markets was favored by 67.9 percent of the growers voting in the referendum, representing 69.5 percent of the total volume of hazelnuts produced by those voting.

The amendments favored by voters and included in this final order authorize the regulation of quality for the purpose of pathogen reduction and the establishment of different outgoing quality regulations for different markets.

USDA also made such changes as were necessary to the Order so that all of the Order’s provisions conform to the effectuated amendments. USDA recommended one clarifying change to the language in the new paragraph §982.45(c), which adds authority to regulate quality. USDA determined that the language as presented in the Notice of Hearing was redundant and, therefore, confusing. USDA revised the language in the new paragraph §982.45(c) so that its intent is more clearly stated. This language is included in the regulatory text of this Order.

The amended marketing agreement was subsequently mailed to all hazelnut handlers in the production area for their approval. The marketing agreement was not approved by handlers representing more than 50 percent of the volume of hazelnuts handled by all handlers during the representative period of July 1, 2016, through June 30, 2017. Consequently, no companion handler agreement will be established.

Small Business Consideration

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), AMS has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this final regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be unduly or disproportionately burdened. Marketing orders and amendments thereto are unique in that they are normally brought about through group action of essentially small entities for their own benefit.

Hazelnut Industry Background and Overview

According to the hearing transcript, there are currently over 800 hazelnut growers in the production area. According to National Agricultural Statistics Service (NASS) data presented at the hearing, 2015 grower receipts averaged $2,800 per ton. With a total 2015 production of 31,000 tons, the farm gate value for hazelnuts in that year totaled $86.8 million ($2,800 per ton multiplied by 31,000 tons). Taking the total value of production for hazelnuts and dividing it by the total number of hazelnut growers provides a return per grower of $108,500. A small grower as defined by the Small Business Administration (SBA) (13 CFR 121.201) is one having annual receipts of less than $750,000 annually. A majority of hazelnut growers are considered small entities under the SBA standards. Record evidence indicates that approximately 98 percent of hazelnut growers are small businesses.

According to the industry, there are 17 hazelnut handlers, four of which handle 80 percent of the crop. While market prices for hazelnuts were not included among the data presented at
the evidence presented at the hearing shows that the amendments would have no burdensome effects on small agricultural producers or firms. In discussing the impacts of the amendments on growers and handlers, record evidence indicates that the authority to establish quality regulations that require hazelnuts to be treated prior to shipment to reduce pathogen load would not significantly impact the majority of handlers. Regulations implemented under that authority could impose additional costs on handlers required to comply with them. However, witnesses testified that establishing mandatory treatment regulations could increase the industry’s credibility and reduce the risk that shipments of substandard product could jeopardize the entire industry’s reputation. Record evidence shows that any additional costs are likely to be offset by the benefits of complying with those requirements.

The record shows that the proposal to add authority to establish different outgoing quality requirements for different markets would, in itself, have no economic impact on growers or handlers of any size. While regulations implemented under that authority could potentially impose additional costs on handlers required to comply with them, the record indicates the benefits of such regulation would outweigh the potential future costs. The record indicates that allowing different regulations for different markets would likely lower the costs to handlers and prevent multiple treatments of hazelnuts while preserving hazelnut quality. This final rule also makes administrative revisions to subpart headings to bring the language into conformance with the Office of Federal Register requirements.

USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule. These amendments are intended to improve the operation and administration of the Order and to assist in the marketing of hazelnuts.

Paperwork Reduction Act

Current information collection requirements for Part 982 are approved by OMB, under 0581–0178 “Vegetable and Specialty Crops.” No changes are anticipated in these requirements as a result of this proceeding. Should any such changes become necessary, they would be submitted to OMB for approval.

As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public-sector agencies.

AMS is committed to complying with the Government Paperwork Elimination Act, which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Civil Justice Reform

The amendments to the Order stated herein have been reviewed under Executive Order 12988, Civil Justice Reform. They are not intended to have retroactive effect. The amendments do not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed no later than 20 days after the date of entry of the ruling.

Order Amending the Order Regulating the Handling of Hazelnuts Grown in Oregon and Washington

Findings and Determinations

The findings and determinations hereinafter set forth are supplementary to the findings and determinations that were previously made in connection with the issuance of the Marketing Order; and all said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in
conflict with the findings and determinations set forth herein.

(a) Findings and Determinations Upon the Basis of the Hearing Record

Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice and procedure effective thereunder (7 CFR part 900), a public hearing was held upon further amendment of Marketing Order No. 982, regulating the handling of hazelnuts grown in Oregon and Washington.

Upon the basis of the record, it is found that:

(1) The Order, as amended, and as hereby further amended, and all of the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

(2) The Order, as amended, and as hereby further amended, regulates the handling of hazelnuts grown in the production area in the same manner as, and if applicable only to, persons in the respective classes of commercial and industrial activity specified in the Order upon which a hearing has been held;

(3) The Order, as amended, and as hereby further amended, is limited in its application to the smallest regional production area that is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act;

(4) The Order, as amended, and as hereby further amended, prescribes, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of hazelnuts grown in Oregon and Washington;

(5) All handling of hazelnuts grown in the production area as defined in the Order is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

(b) Determinations. It is hereby determined that:

(1) Handlers (excluding cooperative associations of growers who are not engaged in processing, distributing, or shipping hazelnuts covered by the order as hereby amended) who, during the period July 1, 2016, through June 30, 2017, handled 50 percent or more of the volume of such hazelnuts covered by said order, as hereby amended, have not signed an amended marketing agreement;

(2) The issuance of this amendatory Order, further amending the aforesaid Order, was favored or approved by at least two-thirds of the growers who participated in a referendum on the question of approval and who, during the period of July 1, 2016, through June 30, 2017 (which has been deemed to be a representative period), have been engaged within the production area in the production of such hazelnuts, such growers having also produced for market at least two-thirds of the volume of such commodity represented in the referendum; and

(3) The issuance of this amendatory Order advances the interests of growers of hazelnuts in the production area pursuant to the declared policy of the Act.

Order Relative to Handling

It is therefore ordered, that on and after the effective date hereof, all handling of hazelnuts grown in Oregon and Washington shall be in conformity to, and in compliance with, the terms and conditions of the said Order as hereby amended as follows:

The provisions of the amendments to the Order contained in the Secretary's Decision issued on September 14, 2017, and published in the September 28, 2017, issue of the Federal Register (82 FR 45208) will be and are the terms and conditions of this order amending the Order and are set forth in full herein.

List of Subjects in 7 CFR Part 982

Hazelnuts, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, 7 CFR part 982 is amended as follows:

PART 982—HAZELNUTS GROWN IN OREGON AND WASHINGTON

1. The authority citation for part 982 continues to read as follows:


[Subpart Redesignated as Subpart A]

2. Redesignate the “Subpart—Order Regulating Handling” as “Subpart A—Order Regulating Handling”.

3. Revise § 982.12 to read as follows:

§ 982.12 Merchantable hazelnuts.

Merchantable hazelnuts means inshell hazelnuts that meet the grade, size, and quality regulations in effect pursuant to § 982.45 and are likely to be available for handling as inshell hazelnuts.

4. Amend § 982.40 by revising paragraph (d) to read as follows:

§ 982.40 Marketing policy and volume regulation.

(d) Grade, size, and quality regulations. Prior to September 20, the Board may consider grade, size, and quality regulations in effect and may recommend modifications thereof to the Secretary.

5. Revise the undesignated center heading prior to § 982.45 to read as follows:

Grade, Size, and Quality Regulation

6. In § 982.45, revise the section heading and add paragraphs (c) and (d) to read as follows:

§ 982.45 Establishment of grade, size, and quality regulations.

(c) Quality regulations. For any marketing year, the Board may establish, with the approval of the Secretary, such minimum quality and inspection requirements applicable to hazelnuts to facilitate the reduction of pathogens as will contribute to orderly marketing or will be in the public interest. In such marketing year, no handler shall handle hazelnuts unless they meet applicable minimum quality and inspection requirements as evidenced by certification acceptable to the Board.

(d) Different regulations for different markets. The Board may, with the approval of the Secretary, recommend different outgoing quality requirements for different markets. The Board, with the approval of the Secretary, may establish rules and regulations necessary and incidental to the administration of this provision.

7. Amend § 982.46 by adding paragraph (d) to read as follows:

§ 982.46 Inspection and certification.

(d) Whenever quality regulations are in effect pursuant to § 982.45, each handler shall certify that all product to be handled or credited in satisfaction of a restricted obligation meets the quality regulations as prescribed.

[Subpart Redesignated as Subpart B and Amended]

8. Redesignate “Subpart—Grade and Size Regulation” as subpart B and revise the heading to read as follows:

Subpart B—Grade and Size Requirements

[Subpart Redesignated as Subpart C]

9. Redesignate “Subpart—Free and Restricted Percentages” as “Subpart C—Free and Restricted Percentages”.

* * * * *
SUMMARY: The Federal Housing Finance Agency (FHFA) is amending its regulation on the Responsibilities of Boards of Directors, Corporate Practices, and Corporate Governance for its regulated entities. The final rule amends the existing regulation pertaining to Federal Home Loan Bank strategic business plans so that it applies as well to the Enterprises, and makes a number of adjustments and conforming changes to the existing regulation. As amended, the regulation requires that the board of directors of each regulated entity have in effect at all times a strategic business plan that describes its strategy for achieving its mission and public purposes. It extends to the Enterprise boards the existing provision requiring the board of each Federal Home Loan Bank to review the strategic business plan at least annually, re-adopt it at least once every three years, and establish reporting requirements for and monitor implementation of the strategic business plan. The final rule adds a new provision regarding current and emerging risks, repeals two outdated provisions of the existing regulation, and makes a conforming change to the Office of Finance Board of Directors regulation.

DATES: The final rule is effective on December 18, 2018.

FOR FURTHER INFORMATION CONTACT: Daniel Callis, Principal Risk Analyst, Office of the Chief Accountant, at Daniel.Callis@fhfa.gov or (202) 649–3448, or Ming-Yuen Meyer-Fong, Office of General Counsel, at Ming-Yuen.Meyer-Fong@fhfa.gov or (202) 649–3078 (these are not toll-free numbers), Federal Housing Finance Agency, Constitution Center, 400 Seventh Street SW, Washington, DC 20219. The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

On April 6, 2018, FHFA published a proposed rule that would amend the existing FHFA regulation on Responsibilities of Boards of Directors, Corporate Practices and Corporate Governance Matters. The proposed rule would amend, and extend to apply to the board of directors of each Enterprise, the existing provision requiring the board of directors for each Federal Home Loan Bank to have in effect at all times a strategic business plan for the entity. It would also require the strategic business plan to: (1) Articulate measurable operating goals; (2) address credit needs identified through ongoing market research and stakeholder consultations; (3) describe significant activities being planned, including any changes to business strategy; (4) be supported by appropriate and timely research; and (5) identify current and emerging risks, including those associated with the entity’s existing activities or new activities. It would also require a board to review the strategic business plan at least annually, re-adopt it at least once every three years, and establish reporting requirements for and monitor implementation of the strategic business plan. The proposed rule would also repeal two outdated provisions, and make a conforming change to the Office of Finance Board of Directors regulation.

II. Summary of Comments and FHFA Responses

FHFA received comments on the proposed rule from Fannie Mae and Freddie Mac (Enterprises) and U.S. Mortgage Insurers (USMI), a trade association comprising various private mortgage insurance companies. The commenters generally agreed with the proposal regarding current and emerging risks, including those associated with the entity’s existing activities or new activities. The commenters also generally agreed that a strategic business plan should have measurable goals and objectives to hold management accountable.

B. Appropriate Balance Between High-Level View and Granular Detail

Comments differed on the appropriate balance between board flexibility to plan from a high-level perspective and at a more detailed level. Two commenters proposed modifying the final rule to permit a board to articulate goals and strategies at a high level, while one commenter supported requirements on the level of individual activities.

The commenters offered specific suggestions to revise the language of the regulation to permit high-level discussion. With respect to proposed § 1239.14(a)(1)(i) and (ii), FHFA received suggestions for the plan to articulate goals and objectives for “strategic activities,” not “for each significant activity and all authorized new activities” as proposed. Another commenter suggested that goals and objectives be articulated for “significant business strategy.”

For proposed § 1239.14(a)(3), one commenter suggested that the requirement should be that the plan describe “significant strategic activities” while another suggested “strategies.” Commenters suggested that the final regulation exclude from strategic planning changes in business strategy not determined “significant.”

For proposed § 1239.14(a)(5), commenters suggested excluding less-than-significant risks from being required to be addressed in the strategic business plan. One commenter...
suggested that the strategic business plan address significant risks associated with significant activities. Another similarly suggested that the rule should not require a strategic business plan to address risks, including significant risks, associated with activities that a board does not determine to be significant.

One commenter expressed concern that requiring the plan to address specific activities could be unworkable due to high numbers of Enterprise activities.

In contrast, another commenter supported strategic planning requirements for individual activities, and questioned a threshold prescribing planning only for “significant” activities, because the metric for “significance” remains too broad, and potentially excludes too much from board scrutiny or oversight. This commenter expressed that strategic planning for individual activities and authorized new activities would facilitate a board’s monitoring and review of individual activities and market footprint. The same commenter also suggested the rule apply metrics such as stress testing to Enterprise activities to assess their risks.

FHFA Response: A strategic business plan articulates a regulated entity’s long-term vision, and aligns it with the entity’s risk management framework, statutory mission, and public purposes. A strategic business plan also articulates a regulated entity’s roadmap for achieving its goals.

The management of a regulated entity shall be “by or under the direction” of its board of directors, and the board has “ultimate responsibility” of oversight over the entity, which responsibility may not be delegated to management. FHFA recognizes that requirements that are too specific may in some instances involve the board unnecessarily in operational details that it could have otherwise determined to delegate in the absence of such requirements. FHFA also recognizes that granular requirements could mean unwieldy numbers of activities for a strategic business plan to address. Given the interest in avoiding board distraction in its strategic planning by unnecessary or unhelpful operational details, FHFA declines to modify the rule to require strategic goals to be articulated at the level of every existing activity or authorized new activity, regardless of the activity’s significance.

On the other hand, requirements that are too high-level may not provide a board with a sufficient view of the risks of the goals and of strategies deployed to achieve those goals. To support board planning at a meaningful level of involvement, FHFA also declines to modify the rule to permit strategic goals to be articulated at the highest level of generality. FHFA seeks an appropriate balance in the final rule, necessary to support a board’s efforts in setting strategic goals, determining a safe and sound strategy to meet those goals, and overseeing execution. The final rule uses a threshold of “significant” activities. A threshold of “significant” activities would avoid requiring a board to engage with activities that the board does not determine are significant. The rule does not require a board to perform, by itself, every task necessary to determine those activities that are significant. Instead, subject to its duties, a board may set parameters for senior management to apply in identifying activities that the board considers to be significant activities. These parameters could relate to the risks posed by an activity, including whether the activity contributes to or deviates from the entity’s strategic goals, statutory mission, and public purposes. They could also relate to any increased scaling of the activity, either planned or in execution.

The final rule does not require specific metrics to address expansion or contraction of activities in response to the entity’s mission, public purposes and market assessment. Subject to its duties under applicable law in the absence of specific regulatory requirements, a board will determine, or oversee the determination of, any such appropriate metrics.

The final rule in the opening provision of § 1239.14(a), which establishes a general requirement for a strategic business plan, is revised to require a strategic business plan to describe how the “significant” business activities of the regulated entity will achieve a regulated entity’s mission and public purposes. Though FHFA did not receive specific comments to the proposed opening provision of § 1239.14(a), FHFA made the final rule revision to the opening provision based on comments it received on this issue.

The final rule is also revised at § 1239.14(a)(1)(i) and (ii) to state that a board’s strategic business plan shall articulate measurable goals and objectives. Also, the proposed reference to “operating” is deleted so that a plan is not required, or limited, to articulate “operating” goals and objectives. Section 1239.14(a)(1)(ii) is revised to clarify that a plan articulate measurable goals and objectives related to “significant” authorized new activities. As a result of this revision, a plan would not be required to address authorized new activities that are not determined to be significant activities. A parallel change was not made to § 1239(a)(1)(i), the provision applying to the Banks. The FHFA regulation covering new business activities process for the Banks already contains a determination that the activity “entails material risks . . .” 12 CFR 1272.1. If FHFA were to amend the regulations regarding Enterprise new activities and new products to include a threshold equivalent to the “significant” activities threshold used in the final rule, FHFA may consider taking a similar approach for the Enterprises in § 1239.14(a)(1)(i) that it does for the Banks in § 1239.14(a)(1)(i). At § 1239.14(a)(3), the revised final rule requires a plan to describe any “significant” changes to business strategy that are planned, and not just any change to business strategy. As a result of this revision, a board is not required to address changes to business strategy that the entity is planning to undertake that it does not determine to be significant.

At § 1239.14(a)(5), the revised final rule requires a strategic business plan to identify current and emerging risks associated with the regulated entity’s “significant” activities, existing or new. The revised final rule also requires that a plan discuss how the entity intends to address such risks, i.e., those risks associated with the entity’s significant activities, while furthering its public purposes and mission in a safe and sound manner. The final rule does not

---

1. See 12 CFR 1239.4(a).

2. This approach is consistent with the standards of other regulators of large financial institutions cited by Freddie Mac in its proposed surveillance guidance cited by the Federal Reserve Board’s recent supervisory guidance (July 2014). 2124.05.3.2 (each firm’s board of directors should “maintain a clearly articulated corporate strategy and institutional risk appetite. The board should set direction and oversight for revenue and profit generation, risk management and control functions, and other areas essential to sustaining the consolidated organization . . .”). Similarly, the Federal Reserve Board’s recent proposed guidance cited by Freddie Mac provides that a “clear strategy includes sufficient detail to enable senior management to identify the firm’s strategic objectives; [and] to create an effective management structure, implementation strategies, plans and budgets for each business line”). 82 FR 37219, 37224 (Aug. 9, 2017). The Federal Reserve Board’s proposed guidance thus provides that a strategic plan is expected to communicate to senior management the board’s priorities, objectives, and strategies in sufficient detail for senior management to allocate resources appropriately to each business line.
require the board to address risks associated with activities that have not been determined to be significant.

C. Differences in Roles Between Board and Management (§ 1239.14(a)(2); § 1239.14(a)(4)(ii))

FHFA received comments that the proposed rule would impose on the board duties more appropriate for management, and that the final rule should preserve the distinct division of roles between board and management.

The comments arose in the context of the proposed requirements that the strategic business plan discuss credit needs and opportunities identified through market research and stakeholder consultation, and be supported by appropriate and timely research and analysis of relevant market developments.

Specific comments suggested that any research and analysis supporting the strategic business plan be as Enterprise management deems appropriate.

FHFA Response: The management of a regulated entity shall be “by or under the direction” of its board of directors, and the board has “ultimate responsibility” of oversight over the entity, which responsibility may not be delegated to management.3 Except for a board’s ultimate responsibility for oversight of the regulated entity, the board has authority to delegate responsibilities to management and to determine the scope of responsibilities delegated to management.

The proposed rule at § 1239.14(a)(2) does not affect a board’s authority to require the board to conduct market research and stakeholder consultations, or prescribe the manner in which such research and consultation must be conducted. The proposed rule does not prohibit a board from delegating market research and stakeholder consultations, consistent with the board’s duties. The final rule adopts § 1239.14(a)(2) as proposed.

Similarly, the proposed rule at § 1239.14(a)(4)(ii) does not require the board to conduct research and analysis of market developments, or prescribe the type of research and analysis. The proposed rule does not affect the board’s authority to determine what research and analysis is appropriate to support the plan. Nor does the proposed rule affect the board’s authority to assign research to senior management, while overseeing that it is done to the board’s satisfaction.

In addition, while Fannie Mae objected to the reference to timely research in § 1239.14(a)(4)(ii), the purpose of that reference is to specify that the supporting research be suitably timed for the plan, and that the research is not stale or expired.

The final rule adopts § 1239.14(a)(4)(ii) as proposed.

D. Comment Suggested Principles-Based Approach Due to Differences Between the Banks and the Enterprises

FHFA received a comment that the minimum requirements for a strategic business plan adapted from existing requirements applying to the Federal Home Loan Banks are not appropriate for the Enterprises. Specifically, the commenter asserted that, unlike the Banks, the Enterprises are SEC-registered, publicly-traded, and operating under New York Stock Exchange requirements. The commenter further noted that the Enterprises are larger than the Banks and securitize mortgages as their core business model.

FHFA Response: The commenter’s point in noting these differences is that the final rule should take a principles-based approach, not a prescriptive approach. The final rule does not prescribe board functions, such as engaging in market research. The revised final rule also does not prohibit the board from delegating functions, other than its ultimate oversight function, to senior management.

In fact, the operative requirement in the revised final rule, which is unchanged from the proposed rule, is for a board to “address and have in effect at all times a strategic business plan for the regulated entity.”

The differences noted by the commenter do not adversely affect the Enterprises. The differences also do not diminish the traditional role that a board plays in setting strategic goals for the entity, and holding management responsible for executing on the plan.

E. The Final Rule Requirements Do Not Apply to Diversity and Inclusion Strategic Plans

FHFA received a comment that the final rule should not apply to diversity and inclusion strategic plans, which are addressed specifically by 12 CFR 1223.21(b), (d), and (e).

FHFA Response: FHFA agrees that the diversity and inclusion strategic plans are subject to separate regulatory requirements. Therefore, this final rule does not apply to such plans. Moreover, the final rule does not prohibit a regulated entity from incorporating its diversity and inclusion strategic plan into its strategic business plan, which is expressly permitted under 12 CFR 1223.21(b)(8).

F. Strategic Business Plan To Address Current and Emerging Risks (§ 1239.14(a)(5))

The commenters also differed on whether the strategic business plan should address current and emerging risks. With respect to proposed § 1239.14(a)(5), FHFA received a comment that, while current risks may be ascertainable, emerging risks may not be knowable at the outset of a multi-year strategic planning process. Another commenter expressed support for a requirement that the strategic business plan address current and emerging risks.

FHFA Response: FHFA acknowledges that while it may be challenging for the board to ascertain emerging risks associated with significant activities at the outset of a multi-year strategic planning process, it should not preclude a board from exercising its duty of care to plan for such risks. A board’s goals in strategic planning includes assessing the entity’s goals to determine whether they align with the entity’s public purposes and mission, and strategies for execution to identify any risks and determine whether the strategies are safe and sound and align with the entity’s risk management framework.4 A core part of a board’s strategic responsibility for the health and prosperity of a company is to look into the future insofar as it can be done, to assess what risks may be approaching.

With the revision discussed above at ILB, the final rule otherwise adopts, as proposed, the provision on emerging risks and furthering the entity’s public purposes and mission in a safe and sound manner.

G. The Final Rule During Conservatorship

A commenter asked how conservatorship and 12 CFR part 1253 (Prior Approval for Enterprise Products) affects the final rule, how FHFA views the relationship between its conservatorship and regulatory obligations, and how its processes and decisions regarding activities and products are consistent with FHFA’s role as conservator. A commenter suggested that FHFA issue guidance on how the final rule would apply to “significant activities” in light of 12 CFR part 1253.

4 A similar approach is taken by the OCC in its Guidelines, cited by Freddie Mac, establishing “heightened standards” for certain large insured financial institutions. Specifically, the OCC guidance provides that the strategic plan cover at a minimum a three-year period and contain “a comprehensive assessment of risks that currently have an impact on the covered bank or that could have an impact on the covered bank during the period covered by the strategic plan.” 12 CFR part 30, App. D, sec. D.1.

3 See 12 CFR 1239.4(a).
FHFA Response: As FHFA noted when it most recently adopted its corporate governance regulation, the regulation was not intended to address conservatorship matters. 80 FR 72327, 72328 (Nov. 19, 2015). Rather, the regulation was intended to address matters of corporate practice and governance at the regulated entities, and was adopted consistent with FHFA’s regulatory authority under the Safety and Soundness Act.

Separately, pursuant to its conservatorship authority, FHFA has provided for Enterprise boards to exercise the functions of management oversight that exist under applicable law and regulation, including FHFA’s corporate governance regulation at 12 CFR part 1239. Although the Enterprises remain in conservatorship, their boards of directors have been operating under FHFA regulations, including most recently 12 CFR part 1239, that govern board members outside of conservatorship, except as modified by the conservator. Therefore, under this final rule, the board of directors at each Enterprise is required to adopt and have in effect a strategic business plan.

The Enterprise new activities process (12 CFR part 1253) and the final rule both reference “new activity.” However, they use the term  for different supervisory purposes. Part 1253 defines new activities inclusively to support determination of new products, while the final rule establishes strategic plan requirements involving “significant” new activities, which is a smaller subset of new activities. In addition, the Enterprise new activities process is separate from the strategic business plan process. For example, the Enterprise new activities process may result in the review and authorization of new activities that are not required to be addressed in the strategic business plan because the board does not determine them significant. Similarly, a strategic business plan may address significant activities that are not new activities. The availability or denial of individual new activities may augment or limit a regulated entity’s tools for meeting its chosen strategic goals. A strategic business plan could help identify significant activities on which the regulated entity plans to rely to achieve its strategic goals. It could also help identify alternative strategies that may be safer and more effective, and to explain the role, relevance, and risks of significant activities that the regulated entity is planning to undertake.

However, FHFA decisions relating to new activities do not affect a board’s process for developing and adopting a strategic business plan. Given that strategic planning and new activities processes operate separately, guidance explaining the connection between the two rules and processes is inappropriate at this time.

III. Final Rule
A. Overview

The final rule retains the general requirement for a strategic business plan to address activities the board determines significant. Clarifying revisions are made to specific provisions.

In addition, the final rule requires a strategic business plan to articulate measurable goals, address credit needs and market opportunities, describe significant activities being planned including significant changes in business strategy, be supported by appropriate and timely research, and identify current and emerging risks. It also requires a board to review the strategic business plan at least annually, re-adopt it at least once every three years, and establish reporting requirements for and monitor implementation of the strategic business plan. The final rule also repeals two outdated provisions that required Bank strategic business plans to include quantitative performance goals for Bank products related to multifamily housing and to community financial institution collateral, and that required related reporting. It also makes a conforming change to the Office of Finance Board of Directors regulation.

B. Section-by-Section Analysis

§ 1239.14(a)—opening provision: The final rule is revised to add “significant” to circumscribe the business activities that a strategic business plan is required to describe. Thus, a board of directors is required to adopt and have in effect at all times a strategic business plan that describes how the “significant” business activities of the regulated entity will achieve its mission and public purposes consistent with its authorizing statute, the Safety and Soundness Act, and, in the case of a Bank, 12 CFR part 1265. The focus of the requirement is on those business activities a board determines significant.

§ 1239.14(a)(1)(i): The final rule deletes “operating” to provide that, in the case of a Bank, a strategic business plan is required to articulate measurable goals and objectives for each significant business activity and all authorized new business activities. As a result of the revision, the focus of the requirement is on measurable goals and objectives for significant activities, both existing and new.

§ 1239.14(a)(2): The final rule adopts paragraph 1239.14(a)(2) as proposed.

§ 1239.14(a)(3): The final rule adds “significant” to provide that a strategic business plan is required to describe any significant activities in which the regulated entity is planning to be engaged, including any significant changes to business strategy or approach that the regulated entity is planning to undertake. As a result of the revision, the requirement to describe any significant activities in which the regulated entity is planning to be engaged includes significant changes to business strategy or approach that the entity is planning to undertake.


§ 1239.14(a)(5): The final rule deletes “including those” and adds “significant” to provide that a strategic business plan is required to identify current and emerging risks associated with the regulated entity’s significant existing activities or new activities, and to discuss how it plans to address such risks while furthering its public purposes and mission in a safe and sound manner. As a result of the revision, the focus of the requirement is on risks associated with the entity’s significant activities, existing or new.

§ 1239.14(b): The final rule adopts § 1239.14(b)(1) and (2) as proposed and makes a conforming change to § 1239.14(b)(3) by deleting “operating” to provide that each board of directors establish management reporting requirements and monitor implementation of the strategic business plan and the goals and objectives contained therein.

§ 1239.14(c)(2): Section 1239.14(c)(2) of the Office of Finance Board of Directors regulation makes a conforming change to update the reference from “§ 1239.31” to “§ 1239.14.” The amendment is adopted as proposed.

C. Consideration of Differences Between the Banks and the Enterprises

When promulgating regulations that relate to the Banks, section 1313(f) of the Safety and Soundness Act requires FHFA to consider the differences between the Banks and the Enterprises with respect to the Banks’ cooperative ownership structure, mission of
providing liquidity to members, affordable housing and community development mission, capital structure, and joint and several liability. 12 U.S.C. 4513(f). FHFA has considered these areas of differences between the Banks and the Enterprises, and has determined that the final rule is unlikely to adversely affect the Banks in these areas of differences.

IV. Paperwork Reduction Act

The final rule does not contain any collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Therefore, FHFA has not submitted any information to the Office of Management and Budget for review.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires an agency to analyze a regulation’s impact on small entities if the regulation is expected to have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). FHFA has considered the impact of this final rule and the General Counsel of FHFA certifies that it is not likely to have a significant economic impact on a substantial number of small entities because it applies only to the regulated entities, which are not small entities for purposes of the Regulatory Flexibility Act.

VI. Congressional Review Act

In accordance with the Congressional Review Act, FHFA has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB). See 5 U.S.C. 804(2).

List of Subjects
12 CFR Part 1239

Administrative practice and procedure, Federal home loan banks, Government-sponsored enterprises, Reporting and recordkeeping requirements.

12 CFR Part 1273

Federal home loan banks, Securities.

Accordingly, for reasons stated in the Supplementary Information, FHFA hereby amends parts 1239 and 1273 of chapter XII of title 12 of the Code of Federal Regulations as follows:

Subchapter B—Regulated Entities

PART 1239—[AMENDED]

1. The authority citation for part 1239 continues to read as follows:

Authority: 12 U.S.C. 1426, 1427, 1432(a), 1436(a), 1440, 4511(b), 4513(a), 4513(b), 4526, and 15 U.S.C. 78oo(b).

2. Add § 1239.14 to subpart C to read as follows:

§ 1239.14 Strategic business plan.

(a) Adoption of strategic business plan. Each board of directors shall adopt and have in effect at all times a strategic business plan for the regulated entity that describes, at a minimum, how the significant business activities of the regulated entity will achieve its mission and public purposes consistent with its authorizing statute, the Safety and Soundness Act, and, in the case of a Bank, part 1265 of this chapter. Specifically, each regulated entity’s strategic business plan shall at a minimum:

(1)(i) In the case of a Bank, articulate measurable goals and objectives for each significant business activity and for all authorized new business activities, which must include plans for maximizing activities that further the Bank’s housing finance and community lending mission, consistent with part 1265 of this chapter;

(ii) In the case of an Enterprise, articulate measurable goals and objectives for each significant existing activity and for significant authorized new activities;

(2) Discuss how the regulated entity will address credit needs and market opportunities identified through ongoing market research and stakeholder consultations;

(3) Describe any significant activities in which the regulated entity is planning to be engaged, including any significant changes to business strategy or approach that the regulated entity is planning to undertake, and discuss how such activities would further the regulated entity’s mission and public purposes;

(4)(i) In the case of a Bank, be supported by appropriate and timely research and analysis of relevant market developments and member and housing associate demand for Bank products and services;

(ii) In the case of an Enterprise, be supported by appropriate and timely research and analysis of relevant market developments; and

(5) Identify current and emerging risks associated with the regulated entity’s significant existing activities or new activities, and discuss how the regulated entity plans to address such risks while furthering its public purposes and mission in a safe and sound manner.

(b) Review and monitoring. Each board of directors shall:

1. Review the regulated entity’s strategic business plan at least annually;

2. Re-adopt the strategic business plan for the regulated entity at least every three years; and

3. Establish management reporting requirements and monitor implementation of the strategic business plan and the goals and objectives contained therein.

§ 1239.31 [Removed and reserved]

3. Remove and reserve § 1239.31.

Subchapter D—Federal Home Loan Banks

PART 1273—[AMENDED]

4. The authority citation for part 1273 continues to read as follows:

Authority: 12 U.S.C. 1431, 1440, 4511(b), 4513, 4514(a), 4526(a).

§ 1273.8 [Amended]

5. Section 1273.8(d)(2) is amended by removing the reference to “§ 1239.31” and adding in its place “§ 1239.14.”


Melvin L. Watt, Director, Federal Housing Finance Agency.

[FR Doc. 2018–22859 Filed 10–18–18; 8:45 am]

BILLING CODE 8070–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No.: FAA–2014–0225; Amdt. No. 91–331E]

RIN 2120–AL39

Amendment of the Prohibition Against Certain Flights in Specified Areas of the Simferopol and Dnipropetrovsk Flight Information Regions (FIRs) (UKFV and UKDV)

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This action extends, with modifications to reflect changed conditions in specified areas of Ukraine, the Special Federal Aviation Regulation (SFAR) prohibiting certain flight operations in the Simferopol Flight Information Region (FIR) (UKFV) and Dnipropetrovsk Flight Information Region (FIR) (UKDV) by all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air
carrier; and operators of U.S.-registered civil aircraft, except where the operator of such aircraft is a foreign air carrier. This action extends the prohibition in specified areas of Ukraine to safeguard against continuing hazards to U.S. civil aviation. However, this action also reduces the scope of the prohibition against flights in the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV) permitting U.S. civil operations to resume in specified areas due to the stabilization of safety and security conditions in the relevant regions of Ukraine.

DATES: This final rule is effective on October 19, 2018.

FOR FURTHER INFORMATION CONTACT: Michael Filippell, Air Transportation Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone 202–267–8166; email michael.e.filippell@faa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

This action extends, with modification to reflect changed conditions in Ukraine, the prohibition against U.S. civil flight operations in specified areas of the Simferopol Flight Information Region (FIR) (UKFV) and Dnipropetrovsk Flight Information Region (FIR) (UKDV) by all U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except where the operator of such aircraft is a foreign air carrier, from October 27, 2018, until October 27, 2020. The FAA assesses that security and safety conditions have sufficiently stabilized in certain regions of Ukraine, thereby reducing the area of hazard to U.S. civil aviation in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV). However, the FAA finds an extension of the prohibition is necessary in other specified areas of Ukraine to safeguard against continuing hazards to civil aviation. The new boundaries of the prohibition are described in the preamble to this final rule. In this action, the FAA retains the lateral limits of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV), for reference as definitions in new paragraph (f) of the final rule.

II. Legal Authority and Good Cause

A. Legal Authority

The FAA is responsible for the safety of flight in the U.S. and for the safety of U.S. civil operators, U.S.-registered civil aircraft, and U.S.-certificated airmen throughout the world. The FAA Administrator’s authority to issue rules on aviation safety is found in title 49, U.S. Code, Subtitle I, sections 106(f) and (g). Subtitle VII of title 49, Aviation Programs, describes in more detail the scope of the agency’s authority. Section 40101(d)(1) provides that the Administrator shall consider in the public interest, among other matters, assigning, maintaining, and enhancing safety and security as the highest priorities in air commerce. Section 40105(b)(1)(A) requires the Administrator to exercise this authority consistently with the obligations of the U.S. Government under international agreements.

This rulemaking is promulgated under the authority described in title 49, U.S. Code, Subtitle VII, Part A, subpart III, section 44701, General requirements. Under that section, the FAA is charged broadly with promoting safe flight of civil aircraft in air commerce by prescribing, among other things, regulations and minimum standards for practices, methods, and procedures that the Administrator finds necessary for safety in air commerce and national security.

This regulation is within the scope of FAA’s authority, because it continues to prohibit the persons described in paragraph (a) of SFAR No. 113, 14 CFR 91.1607, from conducting flight operations in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV) due to the ongoing hazards to the safety of U.S. civil flight operations in certain regions of Ukraine, as described in the preamble to this final rule.

The FAA also finds that this action is fully consistent with the obligations under 49 U.S.C. 40105(b)(1)(A) to ensure that the FAA exercises its duties consistently with the obligations of the United States under international agreements.

B. Good Cause for Immediate Adoption

Section 533(b)(3)(B) of title 5, U.S. Code, authorizes agencies to dispense with notice and comment procedures for rules when the agency for “good cause” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Section 553(b)(3)(B) also authorizes agencies to forgo the notice and comment procedures for good cause found and published with the rule. In this instance, the FAA finds good cause to forgo notice and comment because notice and comment would be impracticable and contrary to the public interest. In addition, it is contrary to the public interest to delay the effective date of this SFAR.

The FAA has identified an ongoing need to maintain the flight prohibition in certain specified areas of Ukraine due to continued safety of flight hazards associated with both Ukraine and Russia air navigation service providers (ANSPs) claiming control of airspace over portions of the Simferopol FIR (UKFV) and due to the ongoing conflict with localized skirmishes within the eastern portion of the Dnipropetrovsk FIR (UKDV). These hazards are further described in the preamble to this rule. To the extent that the rule is based upon classified information, such information is not permitted to be shared with the general public. Also, threats to U.S. civil aviation can evolve rapidly. As a result, the agency’s original proposal could become unsuitable for minimizing the hazards to U.S. civil aviation in the affected airspace during or after the notice and comment process. For these reasons, the FAA finds good cause to forgo notice and comment and any delay in the effective date for this rule.

III. Background

The FAA first published SFAR No. 113, § 91.1607, on April 25, 2014, to prohibit certain flight operations in a portion of the Simferopol FIR (UKFV) by all: U.S. air carriers; U.S. commercial operators; persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except where the operator of such aircraft is a foreign air carrier.1 At that time, the FAA viewed the possibility of civil aircraft receiving confusing and conflicting air traffic control instructions from both Ukrainian and Russian air navigation service providers (ANSPs) when operating in the portion of the Simferopol FIR (UKFV) covered by SFAR No. 113, § 91.1607, as an unsafe condition that presented a potential hazard to U.S. civil flight operations.

On July 18, 2014, the FAA issued a Notice to Airmen (NOTAM) FDC 4/2182, expanding the flight prohibition to the entire Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV), primarily as an immediate response to the shoot-down of Malaysia Airlines flight MH17 on July 17, 2014, while flying over Ukraine at 33,000 feet just west of the Russian border. The FAA determined that the ongoing conflict in the region posed a significant threat to U.S. civil aviation operations in these FIRs. The

1 70 FR 22862.
use of weapons capable of targeting and shooting down aircraft flying on civil air routes at cruising altitudes posed a significantly dangerous threat to civil aircraft flying in the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV). The FAA published a final rule incorporating the expanded flight prohibition into SFAR No. 113, § 91.1607, on December 29, 2014. The FAA extended this flight prohibition on October 27, 2015 and October 27, 2016 due to continuing flight safety concerns regarding conflicting ANSP guidance within the Simferopol FIR (UKFV) and the ongoing conflict in eastern Ukraine within the Dnipropetrovsk FIR (UKDV).

The flight safety concern for the Simferopol FIR (UKFV) at that time was demonstrated by an European Aviation Safety Agency Safety Information Bulletin on February 17, 2016, indicating that ATS routes L851 and M856 could be considered for planning flights in the Simferopol FIR (UKFV), and subsequent Russian Federal Air Transport Agency response in which it asserted that it was responsible for air traffic services in a portion of the Simferopol FIR (UKFV).

Separately, in the Dnipropetrovsk FIR (UKDV), the FAA noted that there was an ongoing risk of skirmishes in the area and a potential for larger-scale fighting in eastern Ukraine involving combined Russian-separatist forces, which could result in civil aircraft being misidentified as a threat and then intercepted or otherwise engaged. In the 2016 final rule, the FAA identified that these combined forces had access to a variety of anti-aircraft weapons, to include man-portable air defense systems (MANPADS) and possibly more advanced surface-to-air missiles (SAMs) that had the capability to engage aircraft at higher altitudes.

IV. Discussion of the Final Rule

Since 2016 the FAA has prohibited operations within the Simferopol FIR (UKFV) by all U.S. civil operators and airmen, in part, due to continuing flight safety concerns regarding the risk of pilots being given conflicting ANSP guidance within the Simferopol FIR (UKFV). Specifically, in 2014, the Russian Federation annexed the Crimean Peninsula and claimed ANSP authority over the Simferopol FIR (UKFV), including airspace over the Black Sea, and deployed a substantial military force on the peninsula, including advanced weapon capabilities to enforce their territorial and airspace claims for portions of the Simferopol FIR (UKFV). Since that time, the Russian Federation has claimed authority over the entire Simferopol FIR (UKFV) and continues to assert authority over the Crimean Peninsula and adjacent waters. However, the International Civil Aviation Organization (ICAO) and other countries do not support these assertions by the Russian Federation and recognize the Ukrainian State Air Traffic Service Enterprise as the ANSP with authority over the Simferopol FIR (UKFV).

The previous flight safety concerns for conflicting ANSP guidance for the Black Sea air routes at a distance offshore from the peninsula within portions of the Simferopol FIR (UKFV) have been addressed by the government of Ukraine. Since the FAA extended the prohibition in SFAR No. 113, § 91.1607, in 2016, the government of Ukraine has established, via its aeronautical information publication (AIP), a restricted airspace area over the Crimean Peninsula and the adjacent territorial sea. In addition, the government of Ukraine has issued flight advisories, prohibitions and other instructions for the safe navigation of civil aircraft, which are published via NOTAMs, reclassified Ukrainian airspace in 2014 as discussed earlier, and improved safety incident reporting procedures to mitigate the risks associated with conflicting ANSP guidance from the Russian Federation over the Black Sea routes offshore from the Crimean Peninsula and over the high seas. Since these actions were implemented, there has been a decrease in safety-related hazards demonstrated by over two years of safe flight operations on the Black Sea air routes by non-U.S. civil operators. Therefore, the FAA assesses that these actions have sufficiently mitigated the hazard to civil aviation operating on the Black Sea air routes to allow U.S. civil flights to resume on those routes. Specifically, the FAA is relaxing the prohibition from the surface to unlimited south and southwest of a line drawn direct from SOBLO (431503N 362298E) to DOLOT (434214N 332819E), direct to SOROK (440628N 324266E), then direct to OTPOL (452738N 310364E). This change will allow U.S. operators and codeshare partners the ability to use, among others, the following Black Sea routes; M856, M854, M860 and L851. Ukrainian air traffic control routing dynamically manages the routing of air traffic in the specified airspace to meet changing operational demands and conditions.

Nevertheless, the government of Ukraine has not mitigated the hazards in all of the Simferopol FIR (UKFV) necessitating a continuing, albeit more limited, flight prohibition. An overwhelming Russian military presence and weapon capabilities continue to be located on the Crimean Peninsula, creating a continuing risk for misidentification of aircraft flying over the Peninsula and in the airspace near the Peninsula. Additionally, Ukraine and Russia continue to assert competing claims of the airspace. For those reasons, and their attendant risk to U.S. civil aircraft operations, the FAA is continuing to prohibit operations by U.S. civil operators and airmen in the Simferopol FIR (UKFV) from the surface to unlimited north and northeast of a line drawn direct from SOBLO (431503N 362298E) to DOLOT (434214N 332819E), direct to SOROK (440628N 324266E), then direct to OTPOL (452738N 310364E). The use of airway M747, which partially overlaps with the line of demarcation for the area of prohibition, is also prohibited. The remaining area of prohibition includes a sufficient buffer from the continuing
hazard associated with operating over the Crimean Peninsula.

B. Dnipropetrovsk Flight Information Region (FIR) (UKDV)

In the Dnipropetrovsk FIR (UKDV) there continues to be an inadvertent risk to civil aviation associated with the ongoing conflict, which involves localized skirmishes and the potential for larger-scale fighting in the eastern portion of the Dnipropetrovsk FIR (UKDV). These skirmishes and a risk for potential larger-scale fighting could lead to the misidentification and/or engagement of civil aviation by separatist air defense forces, as demonstrated by the shoot-down of Malaysia Airlines flight MH17 on July 17, 2014. The majority of military engagements have been in close proximity to the line of conflict in the eastern portion of the Dnipropetrovsk FIR (UKDV). The various military and militia elements in that region have access to a variety of anti-aircraft weapons including MANPADS and possibly more advanced SAMs that have the capability to engage aircraft at higher altitudes. Separatists have demonstrated their ability to use these anti-aircraft weapons by successfully shooting down a number of aircraft during the course of the fighting in eastern Ukraine in 2014. Organization for Security and Cooperation in Europe Special Monitoring Mission to Ukraine unmanned aircraft systems continue to be shot down by SAMs and small arms ground fire, and brought down with GPS jamming in the eastern portion of the Dnipropetrovsk FIR (UKDV).

These threats are concentrated in the eastern portion of the Dnipropetrovsk FIR (UKDV) within the pro-Russian separatist enclave and in close proximity to the line of control that borders the enclave. The anti-aircraft weapons capabilities and deployments of forces associated with the pro-Russian separatists are limited at this time to within the eastern portion of the Dnipropetrovsk FIR (UKDV). While the potential for fluctuating levels of military engagement continues along the line of control in eastern portions of the Dnipropetrovsk FIR (UKDV), the military conflict has begun to stabilize, which reduces the risk of a larger-scale conflict that might extend into the western portion of the Dnipropetrovsk FIR (UKDV).

This results in a reduced risk to civil aviation in the western portion of the Dnipropetrovsk FIR (UKDV), and the FAA is relaxing the area of prohibition to account for the reduced risk.

Therefore, due to the continued threats in the eastern portion of the Dnipropetrovsk FIR (UKDV), the FAA is continuing to prohibit operations by U.S. civil operators and airmen in the Dnipropetrovsk FIR (UKDV) from the surface to unlimited east of a line drawn direct from ABDAR (471802N 351732E) along airway M853 to NIKAD (485946N 355519E), then along airway N604 to GOBUN (501806N 373824E). The use of airways M853 and N604, which partially overlap with the line of demarcation for the prohibition, is also prohibited. This revised area of prohibition includes a sufficient buffer between the conflict region along the Ukraine-Russia border, including known weapons that may be threats to aviation, and the portions of the Dnipropetrovsk FIR (UKDV) where U.S. civil flights are permitted to resume.

Based on the reduced scope of the prohibition, U.S. operators and airmen are permitted to conduct operations in the western portion of the Dnipropetrovsk FIR (UKDV) from the surface to unlimited west of a line drawn direct from ABDAR (471802N 351732E) along airway M853 to NIKAD (485946N 355519E), then along airway N604 to GOBUN (501806N 373824E), which previously had been prohibited.

In addition, due to the relatively close proximity of the approach and departure routes of three airports to the new boundary of the prohibition flight area, the FAA has added an exception for takeoffs and landings. This exception permits operations within the flight prohibition area of the Dnipropetrovsk FIR (UKDV), to the extent necessary to takeoff and land at three specified airports, subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Ukraine: Kharkiv International Airport (UKHH); Dnipropetrovsk International Airport (UKDD); and Zaporizhzhia International Airport (UKDE). The FAA has determined these operations can be conducted with minimal additional risk due to the sufficient distance provided by the specified prohibition boundary line as a buffer from the area of fighting and associated weapons capabilities.

Therefore, as a result of the significant continuing risk to the safety of U.S. civil aviation in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV), the FAA extends the expiration date of SFAR No. 113, § 91.1607, from October 27, 2018, to October 27, 2020, to maintain the prohibition on flight operations in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV) by foreign carriers; U.S. commercial operators; persons exercising the privileges of an airmen certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and operators of U.S.-registered civil aircraft, except where the operator is a foreign air carrier. While the FAA’s flight prohibition does not apply to foreign air carriers, DOT codeshare authorizations prohibit foreign air carriers from carrying a U.S. codeshare partner’s code on a flight segment that operates in airspace for which the FAA has issued a flight prohibition. The FAA is also retaining the lateral limits of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV), which are recognized by ICAO, for reference as definitions in new paragraph (f) of the final rule.

The FAA will continue to actively monitor the situation and evaluate the extent to which U.S. civil operators and airmen may be able to operate safely in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV). Amendments to SFAR No. 113, § 91.1607, may be appropriate if the risk to aviation safety and security changes.

The FAA may amend or rescind SFAR No. 113, § 91.1607, as necessary, prior to its expiration date.

The FAA is incorporating minor editorial changes for clarifying purposes in § 91.1609, including correcting the title of the FIR and clarifying the procedure for considering approval and exemption requests. These changes are consistent with other recently published SFARs. The FAA is also republishing the details concerning the approval and exemption processes in Sections V and VI of this preamble so that interested persons will be able to refer to this final rule for all relevant information regarding SFAR No. 113.

V. Approval Process Based on a Request From a Department, Agency, or Instrumentality of the United States Government

A. Approval Process Based on an Authorization Request From a Department, Agency, or Instrumentality of the United States Government

In some instances, U.S. Government departments, agencies, or instrumentalities may need to engage U.S. civil aviation to support their activities in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV). The FAA is revising the approval process for SFAR No. 113, § 91.1607, to make it consistent with the approval process of more recently published flight prohibition SFARs. If a department, agency, or instrumentality of the U.S. Government determines that it has a
The critical need to engage any person covered under SFAR No. 113, § 91.1607, including a U.S. air carrier or commercial operator, to conduct a charter to transport civilian or military passengers or cargo, or other operations, in specified areas of the Simferopol FIR (UKFV) or Dnipropetrovsk FIR (UKDV), that department, agency, or instrumentality may request the FAA to approve persons covered under SFAR No. 113, § 91.1607, to conduct such operations.

An approval request must be made directly by the requesting department, agency, or instrumentality of the U.S. Government to the FAA’s Associate Administrator for Aviation Safety in a letter signed by an appropriate senior official of the requesting department, agency, or instrumentality. The FAA will not accept or process requests for approval by anyone other than the requesting department, agency, or instrumentality. In addition, the senior official signing the letter requesting FAA approval on behalf of the requesting department, agency, or instrumentality must be sufficiently highly placed within the organization to demonstrate that the senior leadership of the requesting department, agency, or instrumentality supports the request for approval and is committed to taking all necessary steps to minimize operational risks to the proposed flights. The senior official must also be in a position to: (1) Attest to the accuracy of all representations made to the FAA in the request for approval and (2) ensure that any subject from the requesting U.S. Government department, agency, or instrumentality described in the request for approval is in fact brought to bear and is maintained over time. Unless justified by exigent circumstances, requests for approval must be submitted to the FAA no less than 30 calendar days before the date on which the requesting department, agency, or instrumentality wishes the proposed operations to commence.

The letter must be sent to the Associate Administrator for Aviation Safety, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591. Electronic submissions are acceptable, and the requesting entity may request that the FAA notify it electronically as to whether the approval request is granted. If a requestor wishes to make an electronic submission to the FAA, the requestor should contact the Air Transportation Division, Flight Standards Service, at (202) 267–8166, to obtain the appropriate email address. A single letter may request approval from the FAA for multiple persons covered under SFAR No. 113, § 91.1607, and/or for multiple flight operations. To the extent known, the letter must identify the person(s) expected to be covered under the SFAR on whose behalf the U.S. Government department, agency, or instrumentality is seeking FAA approval, and it must describe—

- The proposed operation(s), including the nature of the mission being supported;
- The service to be provided by the person(s) covered under the SFAR;
- To the extent known, the specific locations in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV) where the proposed operation(s) will be conducted, including, but not limited to, the flight path and altitude of the aircraft while it is operating in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV) and the airports, airfields and/or landing zones at which the aircraft will take-off and land; and
- The method by which the department, agency, or instrumentality will provide, or how the operator will otherwise obtain, current threat information and an explanation of how the operator will integrate this information into all phases of the proposed operations (i.e., pre-mission planning and briefing, in-flight, and post-flight phases).

The request for approval must also include a list of operators with whom the U.S. Government department, agency, or instrumentality requesting FAA approval has a current contract(s), grant(s), or cooperative agreement(s) (or its prime contractor has a subcontract(s)) for specific flight operations in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV). Additional operators may be identified to the FAA at any time after the FAA approval is issued. However, all additional operators must be identified to, and obtain an Operations Specification (OpSpec) or Letter of Authorization (LOA), as appropriate, from the FAA for operations in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV), before such operators commence such operations. The approval conditions discussed below apply to any such additional operators. Updated lists should be sent to the email address to be obtained from the Air Transportation Division, by calling (202) 267–8166. If an approval request includes classified information, requestors may contact Aviation Safety Inspector Michael Filippelli for instructions on submitting it to the FAA. His contact information is listed in the FOR FURTHER INFORMATION CONTACT section of this final rule.

FAA approval of an operation under SFAR No. 113, § 91.1607, does not relieve persons subject to this SFAR of their responsibility to comply with all applicable FAA rules and regulations. Operators of civil aircraft must comply with the conditions of their certificate, OpSpecs, and LOAs, as applicable. Operators must also comply with all rules and regulations of other U.S. Government departments or agencies that may apply to the proposed operation(s), including, but not limited to, regulations issued by the Transportation Security Administration.

B. Approval Conditions

If the FAA approves the request, the FAA’s Aviation Safety Organization will send an approval letter to the requesting department, agency, or instrumentality informing it that the FAA’s approval is subject to all of the following conditions:

1. The approval will stipulate those procedures and conditions that limit, to the greatest degree possible, the risk to the operator, while still allowing the operator to achieve its operational objectives.

2. Before any approval takes effect, the operator must submit to the FAA:

   a. A written release of the U.S. Government from all damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising out of or related to the approved operations in the Simferopol FIR (UKFV) and/or Dnipropetrovsk FIR (UKDV); and
   b. The operator’s written agreement to indemnify the U.S. Government with respect to any and all third-party damages, claims, and liabilities, including without limitation legal fees and expenses, relating to any event arising from or related to the approved operations in specified areas of the Simferopol FIR (UKFV) and/or Dnipropetrovsk FIR (UKDV),

3. Other conditions that the FAA may specify, including those that may be imposed in OpSpecs or LOAs, as applicable.

The release and agreement to indemnify do not preclude an operator from raising a claim under an applicable non-premium war risk insurance policy issued by the FAA under chapter 443 of title 49, U.S. Code.

If the FAA approves the proposed operation(s), the FAA will issue an OpSpec or LOA, as applicable, to the operator(s) identified in the original request authorizing it to conduct the approved operation(s), and will notify
the department, agency, or instrumentality that requested the FAA’s approval of any additional conditions beyond those contained in the approval letter.

VI. Information Regarding Petitions for Exemption

Any operations not conducted under an approval issued by the FAA through the approval process set forth previously must be conducted under an exemption from SFAR No. 113, § 91.1607. A petition for exemption must comply with 14 CFR part 11 and requires exceptional circumstances beyond those contemplated by the approval process set forth previously. In addition to the information required by 14 CFR 11.81, at a minimum, the requestor must describe in its submission to the FAA—

- The proposed operation(s), including the nature of the operation;
- The service to be provided by the person(s) covered by the SFAR;
- The specific locations in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV) where the proposed operation(s) will be conducted, including, but not limited to, the flight path and altitude of the aircraft while it is operating in specified areas of the Simferopol FIR (UKFV) and Dnipropetrovsk FIR (UKDV) and the airports, airfields and/or landing zones at which the aircraft will take-off and land;
- The method by which the operator will obtain current threat information, and an explanation of how the operator will integrate this information into all phases of its proposed operations (i.e., pre-mission planning and briefing, in-flight, and post-flight phases); and
- The plans and procedures that the operator will use to minimize the risks identified in the preamble of this rule, to the proposed operations, so that granting the exemption would not adversely affect safety or would provide a level of safety at least equal to that provided by this SFAR. The FAA has found these, organized plans and procedures of this nature to be helpful in facilitating the agency’s safety evaluation of petitions for exemption from flight prohibition SFARs.

Additionally, the release and agreement to indemnify, as referred to previously, are required as a condition of any exemption that may be issued under SFAR No. 113, § 91.1607.

The FAA recognizes that operations that may be affected by SFAR No. 113, § 91.1607, may be planned for the governments of other countries with the support of the U.S. Government. While these operations will not be permitted through the approval process, the FAA will consider exemption requests for such operations on an expedited basis and prior to any private exemption requests.

VII. Regulatory Notices and Analyses

Changes to Federal regulations must undergo several economic analyses. First, Executive Orders 12866 and 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 603 et seq., requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39), as amended, 19 U.S.C. Chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, the Trade Agreements Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as codified in 2 U.S.C. Chapter 13, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble summarizes the FAA’s analysis of the economic impacts of this final rule.

In conducting these analyses, the FAA has determined that this final rule has benefits that justify its costs. This rule is a significant regulatory action, as defined in section 3(f) of Executive Order 12866, as it raises novel policy issues contemplated under that Executive Order. As notice and comment under 5 U.S.C. 553 are not required for this final rule, the regulatory flexibility analyses described in 5 U.S.C. 603 and 604 regarding impacts on small entities are not required. This rule will not create unnecessary obstacles to the foreign commerce of the United States. This rule will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector, by exceeding the threshold identified previously.

A. Regulatory Evaluation

On April 25, 2014, the FAA published SFAR No. 113 prohibiting flight operations in part of the Simferopol FIR (UKFV) by U.S. air carriers and airmen because of conflicting airspace claims between Ukraine and the Russian Federation owing to the Russian annexation of the Crimean Peninsula. The FAA expanded this prohibition to the entire Simferopol FIR (UKFV) and also to the Dnipropetrovsk FIR (UKDV), first by NOTAM (July 18, 2014 (UTC)) and then by rule (79 FR 77857, December 29, 2014), owing to conflict between Ukraine military forces and pro-Russian separatists. On October 27, 2015 (80 FR 65621) and October 27, 2016 (81 FR 74671), the FAA further extended this prohibition. The FAA now proposes to extend the prohibition for another two years, but only for portions of the Simferopol (UKFV) and Dnipropetrovsk (UKDV) FIRs where there is a continuing hazard to civil aviation. The FAA is extending the prohibition against U.S. civil operations over the Crimean peninsula in the Simferopol FIR (UKFV), but is permitting U.S. civil operations over four Black Sea routes, sufficiently offshore from the Crimea Peninsula, and over the high seas, due to a stabilization in the security conditions on these routes. In addition, the FAA is extending the prohibition in the eastern part of the Dnipropetrovsk FIR (UKDV), but is permitting U.S. civil operations from the surface to unlimited in the western portion of the Dnipropetrovsk FIR (UKDV). The FAA is also permitting, by exception, takeoffs and landings at three Ukrainian international airports due to proximity of the arrival and departure routes to the area of prohibition within the Dnipropetrovsk FIR (UKDV).

As was noted in the most recent previous amendment to SFAR No. 113, § 91.1607 (81 FR 74671, October 27, 2016), almost all U.S. operators already had voluntarily ceased their operations in these FIRs prior to the issuance of the FAA NOTAM on July 18, 2014 (UTC), which prohibited U.S. civil flight operations in these two FIRs in their entirety. Owing to the continuing hazards to civil flight operations outlined in the preamble, the FAA believes that few, if any, U.S. operators presently seek to conduct operations in the eastern portion of the Dnipropetrovsk FIR (UKDV), or over the Crimean peninsula within the Simferopol FIR (UKFV) in which the FIR continues to prohibit U.S. operations. The FAA notes that since April 25, 2014, when U.S. operators and
Airmen were first prohibited from conducting operations in a portion of the Simferopol FIR (UKFV), the FAA has not received any requests for approval or petitions for exemption to conduct operations in either the Simferopol FIR (UKFV) or Dnipropetrovsk FIR (UKDV). Accordingly, where U.S. operations continue to be prohibited the FAA believes incremental costs will be minimal and exceeded by the benefits of avoiding the deaths, injuries, and/or property damage that would result from a U.S. operator’s aircraft being shot down (or otherwise damaged) while operating in either the Dnipropetrovsk FIR (UKDV) or the Simferopol FIR (UKFV).

As noted in the sections above, the Ukraine ANSP has implemented risk mitigation measures to address safety hazards over the Black Sea routes and on the high seas. These measures have resulted in a significant decrease in safety-related hazards in that part of the Simferopol FIR (UKFV) as shown by over two years of safe flight operations by non-U.S. civil operators on the Black Sea air routes. In the Dnipropetrovsk FIR (UKDV), the deployments of forces associated with the pro-Russian separatists are at this time limited to the eastern part, reducing the risk of a larger-scale conflict that might extend into the western portion of the Dnipropetrovsk FIR (UKDV) and thereby reducing risk to U.S. civil aviation in the western portion. The FAA believes that lifting the prohibition on U.S. civil operations in those parts of the two FIRs will be socially cost-beneficial because it may result in the resumption of safe U.S. civil operations.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act, in 5 U.S.C. 603, requires an agency to prepare an initial regulatory flexibility analysis describing impacts on small entities whenever an agency is required by 5 U.S.C. 553, or any other law, to publish a general notice of proposed rulemaking for any proposed rule. Similarly, 5 U.S.C. 604 requires an agency to prepare a final regulatory flexibility analysis when an agency issues a final rule under 5 U.S.C. 553, after being required by that section or any other law to publish a general notice of proposed rulemaking. The FAA found good cause to forgo notice and comment and any delay in the effective date for this rule. As notice and comment under 5 U.S.C. 553 are not required in this situation, the regulatory flexibility analyses described in 5 U.S.C. 603 and 604 are not required.

G. International Trade Impact Assessment

The Trade Agreements Act of 1979 (Pub. L. 96–39) prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to this Act, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The FAA has assessed the potential effect of this final rule and determined that its purpose is to protect the safety of U.S. civil aviation from hazards to their operations in the eastern part of the Dnipropetrovsk FIR (UKDV) and over specified areas of the Crimean Peninsula within the Simferopol FIR (UKFV), locations outside the U.S. Therefore, the rule is in compliance with the Trade Agreements Act of 1979.

D. Unfunded Mandates Assessment

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of $100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a “significant regulatory action.” The FAA currently uses an inflation-adjusted value of $155.0 million in lieu of $100 million. This final rule does not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

E. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new requirement for information collection associated with this immediately adopted final rule.

F. International Compatibility and Cooperation

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA’s policy to conform to ICAO Standards and Recommended Practices to the maximum extent practicable. The FAA has determined that there are no ICAO Standards and Recommended Practices that correspond to this regulation.

G. Environmental Analysis

The FAA has analyzed this action under Executive Order 12114, Environmental Effects Abroad of Major Federal Actions (44 FR 1957, January 4, 1979), and DOT Order 5610.1C, Paragraph 16. Executive Order 12114 requires the FAA to be informed of environmental considerations and take those considerations into account when making decisions on major Federal actions that could have environmental impacts anywhere beyond the borders of the United States. The FAA has determined that this action is exempt pursuant to Section 2–5(a)(ii) of Executive Order 12114 because it does not have the potential for a significant effect on the environment outside the United States.

In accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures,” paragraph 8–6(c), FAA has prepared a memorandum for the record stating the reason(s) for this determination; this memorandum has been placed in the docket for this rulemaking.

VIII. Executive Order Determinations

A. Executive Order 13132, Federalism

The FAA has analyzed this rule under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action would not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have Federalism implications.

B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use

The FAA analyzed this rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it would not be a “significant energy action” under the executive order and would not be likely to have a significant adverse effect on the supply, distribution, or use of energy.

C. Executive Order 13609, Promoting International Regulatory Cooperation

Executive Order 13609, Promoting International Regulatory Cooperation,
(77 FR 26413, May 4, 2012) promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

D. Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This rule is not subject to the requirements of E.O. 13771 (82 FR 9339, Feb. 3, 2017) because it is issued with respect to a national security function of the United States.

IX. Additional Information

A. Availability of Rulemaking Documents

An electronic copy of a rulemaking document may be obtained from the internet by—

- Searching the Federal Document Management System (FDMS) Portal (http://www.regulations.gov);
- Visiting the FAA’s Regulations and Policies web page at http://www.faa.gov/regulations_policies; or

Copies may also be obtained by sending a request (identified by amendment or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267–9677.

Except for classified material, all documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the internet through the Federal Document Management System Portal referenced previously.

B. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121) (set forth as a note to 5 U.S.C. 601) requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the persons listed under the FOR FURTHER INFORMATION CONTACT heading at the beginning of the preamble. To find out more about SBREFA on the internet, visit http://www.faa.gov/regulations_policies/rulemaking/sbrea_act/

List of Subjects in 14 CFR Part 91

Air traffic control, Aircraft, Airmen, Airports, Aviation safety, Freight, Ukraine.

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations, part 91, as follows:

PART 91—GENERAL OPERATING AND FLIGHT RULES

1. The authority citation for part 91 continues to read as follows:


2. Revise § 91.1607 to read as follows:

§ 91.1607 Special Federal Aviation Regulation No. 113—Prohibition Against Certain Flights in the Simferopol Flight Information Region (FIR) (UKFV) and the Dnipropetrovsk Flight Information Region (FIR) (UKDV).

(a) Applicability. This Special Federal Aviation Regulation (SFAR) applies to the following persons:

(1) All U.S. air carriers and U.S. commercial operators;

(2) All persons exercising the privileges of an airman certificate issued by the FAA, except when such persons are operating U.S.-registered aircraft for a foreign air carrier; and

(3) All operators of U.S.-registered civil aircraft, except where the operator of such aircraft is a foreign air carrier.

(b) Flight prohibition. Except as provided in paragraphs (c) and (d) of this section, no person described in paragraph (a) of this section may conduct flight operations in the following specified areas of the Simferopol FIR (UKFV) or the Dnipropetrovsk FIR (UKDV)—

(1) Operations within the Simferopol FIR (UKFV) are prohibited from the surface to unlimited, north and northeast of a line drawn direct from SOBLO (431503N 362298E) to DOLOT (342214N 332819E), direct to SOROK (440628N 324260E), then direct to OTPOL (452736N 313064E). This prohibition applies to airways M747.

(2) Operations within the Dnipropetrovsk FIR (UKDV) are prohibited from the surface to unlimited, east of a line drawn direct from ABDAR (471802N 351732E) along airway M853 to NIKAD (485946N 355519E), then along airway N604 to GOBUN (501806N 373824E). This prohibition applies to airways M853 and N604.

(c) Permitted operations. This section does not prohibit persons described in paragraph (a) of this section from conducting flight operations within either flight prohibition, as described in paragraph (b) of this section under the following circumstances:

(1) Operations are permitted within the flight prohibition area of the Dnipropetrovsk Flight Information Region (FIR) (UKDV), as described in paragraph (b)(2) of this section, to the extent necessary to takeoff and land at the following three airports, subject to the approval of, and in accordance with the conditions established by, the appropriate authorities of Ukraine:

(i) Kharkiv International Airport (UKHH);

(ii) Dnipropetrovsk International Airport (UKDD); and

(iii) Zaporizhzhia International Airport (UKDE).

(2) Operations are permitted within the flight prohibition areas described in paragraph (b)(1) or (2) of this section provided that such flight operations are conducted under a contract, grant, or cooperative agreement with a department, agency, or instrumentality of the U.S. Government (or under a subcontract between the prime contractor of the department, agency, or instrumentality and the person described in paragraph (a) of this section) with the approval of the FAA, or under an exemption issued by the FAA. The FAA will consider requests for approval or exemption in a timely manner, with the order of preference being: first, for those operations in support of U.S. Government-sponsored activities; second, for those operations in support of government-sponsored activities of a foreign country with the support of a U.S. Government department, agency, or instrumentality; and third, for all other operations.

(d) Emergency situations. In an emergency that requires immediate decision and action for the safety of the flight, the pilot in command of an aircraft may deviate from this section to the extent required by that emergency. Except for U.S. air carriers and commercial operators that are subject to the requirements of 14 CFR part 119, 121, 125, or 135, each person who deviates from this section must, within 10 days of the deviation, excluding Saturdays, Sundays, and Federal
c so that a report is submitted to the responsible Flight Standards office a complete description of the deviation and the operations of the aircraft involved in the deviation, including a report of the operations of the aircraft SFAR as necessary. The FAA may amend, rescind, or extend this

52962 Federal Register / Vol. 83, No. 203 / Friday, October 19, 2018 / Rules and Regulations

I. Introduction
On October 10, 2018, Hurricane Michael made landfall on the Florida Panhandle. The storm and subsequent flooding have displaced individuals and businesses and disrupted communications and transportation across the affected region. We are adopting these interim final temporary rules to address the needs of companies directly or indirectly affected by Hurricane Michael or its aftermath that are subject to reporting obligations pursuant to Regulation Crowdfunding or Regulation A.

Section 28 of the Securities Act provides that the Commission may, by rule or regulation, “conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision or provisions of this title or of any rule or regulation issued under this title, to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.” 4

II. Temporary Relief From Filing

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 227 and 230

[Release No. 33–10567]

Regulation Crowdfunding and Regulation A Relief and Assistance for Victims of Hurricane Michael

AGENCY: Securities and Exchange Commission.

ACTION: Interim final temporary rule.

SUMMARY: We are adopting interim final temporary rules for issuers subject to reporting obligations pursuant to Regulation Crowdfunding and Regulation A in order to address the needs of companies directly or indirectly affected by Hurricane Michael. The temporary rules extend the filing deadlines for specified reports and forms due pursuant to Regulation Crowdfunding and Regulation A for certain issuers.

DATES: These rules are effective from October 19, 2018 through November 23, 2018, except that amendatory instruction 1 revising the authority provisions of this title to the extent that such exemption is necessary or appropriate in the public interest, and is consistent with the protection of investors.” 4

Accordingly, pursuant to Section 28 of the Securities Act, we are adopting interim final temporary rules providing that an issuer subject to the reporting

3 See Rule 202(c) of Regulation Crowdfunding, 17 CFR 227.202(c).

4 15 U.S.C. 77a et seq.

5 See Rule 257(f) of Regulation A. 17 CFR 230.257(f).

6 17 CFR 227 et seq.
requirements of either Regulation Crowdfunding or Regulation A is exempt from any requirement to file specified reports or forms with the Commission where the conditions below are satisfied:

(a) The issuer is not able to meet a filing deadline due to Hurricane Michael or its aftermath;
(b) The issuer files with the Commission, on or before November 23, 2018, the report or form required to be filed pursuant to either Regulation Crowdfunding or Regulation A during the period from and including October 10, 2018 to and including November 21, 2018; and

(c) In any such report or form, the issuer discloses that it is relying on the interim final temporary rules and states the reasons why, in good faith, it could not file such report or form on a timely basis.

For Regulation Crowdfunding, the relief includes annual reports on Form C–AR, progress updates on Form C–U, and termination reporting on Form C–TR. For Regulation A, the relief includes post-qualification amendments required at least every 12 months after the qualification date to include updated financial statements, annual reports on Form 1–K, semi-annual reports on Form 1–SA, special financial reports on Forms 1–K or 1–SA, current reports on Form 1–U, and exit reports on Form 1–Z.

III. Economic Analysis

Regulation Crowdfunding and Regulation A permit offers and sales of securities without registration under the Securities Act, subject to certain limitations and conditions, including compliance with ongoing reporting requirements. Based on staff analysis, between June 19, 2015 (the effective date of the most recent Regulation A amendments) and September 30, 2018, approximately 244 filers had Regulation A offering statements qualified by the Commission, excluding withdrawn offerings. Approximately 1,067 issuers initiated Regulation Crowdfunding offerings with Form C filings between May 16, 2016 and September 30, 2018, excluding issuers that have withdrawn offerings.

filings between May 16, 2016 and September 30, 2018, excluding withdrawn offerings. We lack the data to estimate the number of investors in Regulation A or Regulation Crowdfunding offerings that could be affected if issuers rely on the relief provided by the interim final temporary rules, because information on the number of investors is generally not required to be disclosed in periodic or current reports required under Regulation A or in periodic reports or progress updates required under Regulation Crowdfunding.

We are mindful of the costs and benefits of the interim final temporary rules. We believe the interim final temporary rules will benefit issuers that have an obligation to file specified reports with the Commission pursuant to either Regulation Crowdfunding or Regulation A and have been adversely affected by Hurricane Michael or its aftermath by permitting them to take additional time to meet their reporting obligations. We expect the relief provided by the interim final temporary rules will benefit issuers that, absent the relief, would not be able to avail themselves of the exemption from registration under Regulation Crowdfunding or Regulation A because the timely filing of required reports is a condition to the exemptions. In the absence of this relief, issuers could incur prohibitively high costs in an attempt to meet filing deadlines given the lack of communications, transportation, electricity, facilities, and available staff and professional advisors.

The requirement for an issuer to disclose that it is relying on Rule 202(c) of Regulation Crowdfunding or Rule 257(f) of Regulation A and to state the reasons why, in good faith, it could not file a report or form on a timely basis may impose minimal additional costs on issuers availing themselves of this relief. However, we believe that these minimal costs are justified in light of the significant negative implications of not being able to rely on the exemption and the prohibitively high costs an issuer may incur in attempting to file in a timely manner.

We also acknowledge that there may be costs imposed on investors, intermediaries, and other market participants due to delayed access to information about offerings conducted in reliance on Regulation A and Regulation Crowdfunding. Generally, reporting requirements strengthen investor protection and decrease the extent of information asymmetries between issuers and investors. Ongoing reporting provides investors with periodically updated information, allowing them to assess investment opportunities based on the information provided and their level of risk tolerance, resulting in better informed investment decisions and improved allocative efficiency. Given that the interim final temporary rules allow for delayed reporting for a limited time period and only under specified conditions, we do not believe such costs will be significant.

The interim final temporary rules will not substantially affect competition or capital formation. We acknowledge the possibility that the interim final temporary rules may have a minor impact on efficiency. On the one hand, as noted above, the delay in reporting could marginally affect allocative efficiency to the extent that it allows information asymmetries between investors and issuers to persist for the length of time of the delay. On the other hand, we expect efficiency gains to the extent that the interim final temporary rules allow issuers to continue to rely on either of the exemptions from registration that would not be available if one of the required reports that is a condition to the exemptions was not filed in a timely manner, or to the extent the issuers are able to avoid paying a premium to service providers in an attempt to file in a timely manner by delaying reporting during the specified relief period.

As an alternative to the relief specified in the interim final temporary rules, we could have considered a longer or shorter relief period. While a shorter period would have reduced the costs to investors of asymmetric information, it would also reduce the benefits of the interim final temporary rules to issuers. Similarly, a longer period would increase the costs to investors. We believe that the approximately six-week delay in the interim final temporary rules is appropriate given the potential impact Hurricane Michael or its aftermath could have on the efforts of companies to meet filing deadlines pursuant to Regulation Crowdfunding and Regulation A.

IV. Procedural and Other Matters

The Administrative Procedure Act (“APA”) generally requires an agency to
publish notice of a rulemaking in the Federal Register and provide an opportunity for public comment. This requirement does not apply, however, if the agency “for good cause finds . . . that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.” 11 The APA also generally requires that an agency publish an adopted rule in the Federal Register at least 30 days before it becomes effective. This requirement does not apply, however, if the agency finds good cause for making the rule effective sooner.12

Given the temporary nature of the relief contemplated by the interim final temporary rules and the significant and immediate impact of Hurricane Michael and its aftermath on issuers in affected areas, as discussed above, the Commission finds that good cause exists to dispense with notice and comment as impracticable and unnecessary, and to act immediately to amend Rule 202 of Regulation Crowdfunding and Rule 257 of Regulation A.13 Further, the interim final temporary rules will not affect the burden or cost estimates associated with existing collections of information under Regulation Crowdfunding and Regulation A for purposes of the Paperwork Reduction Act of 1995.14

V. Statutory Basis and Text of Amendments

We are adopting amendments to Rule 202 of Regulation Crowdfunding and Rule 257 of Regulation A under the authority set forth in the Securities Act (15 U.S.C. 77a et seq.), particularly, Section 28 thereof.

List of Subjects

17 CFR Part 227

Crowdfunding, Funding portals, Intermediaries, Reporting and recordkeeping requirements, Securities.

17 CFR Part 230

Reporting and recordkeeping requirements, Securities.

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 227—REGULATION CROWDFUNDING, GENERAL RULES AND REGULATIONS

1. The authority citation for part 227 is revised to read as follows:


2. Amend § 227.202 by adding paragraph (d) to read as follows:

§ 227.202 Ongoing reporting requirements.

* * * * *

(d) Temporary relief from certain reporting requirements. (1) An issuer that is not able to meet a filing deadline for any report or form required to be filed by this section, 17 CFR 227.203(a)(3)), or 17 CFR 227.203(b) during the period from and including October 10, 2018 to and including November 21, 2018 due to Hurricane Michael and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 23, 2018.

(2) In any report or form filed pursuant to paragraph (d)(1) of this section, the issuer must disclose that it is relying on this paragraph (g) and state the reasons why, in good faith, it could not file such report or form on a timely basis.

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

3. The authority citation for part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77ss, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78o–7 note, 78l, 78w, 78ll(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

4. Amend § 230.257 by adding paragraph (g) to read as follows:

§ 230.257 Periodic and current reporting; exit report.

(g) Temporary relief from ongoing reporting requirements. (1) An issuer that is not able to meet a filing deadline for any report or form required to be filed by 17 CFR 230.252(d)(2)(i) or this section during the period from and including October 10, 2018 to and including November 21, 2018 due to Hurricane Michael and its aftermath

shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 23, 2018.

(2) In any report or form filed pursuant to paragraph (g)(1) of this section, the issuer must disclose that it is relying on this paragraph (g) and state the reasons why, in good faith, it could not file such report or form on a timely basis.

By the Commission.

Brent J. Fields,
Secretary.

[FR Doc. 2018–22930 Filed 10–17–18; 4:15 pm]
BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. FDA–2018–N–3684]

Medical Devices; Anesthesiology Devices; Classification of the Positive Airway Pressure Delivery System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the positive airway pressure delivery system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the positive airway pressure delivery system’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 19, 2018. The classification was applicable on June 5, 2018.

FOR FURTHER INFORMATION CONTACT: Deepika Arora Lakhani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2543, Silver Spring, MD 20993–0002, 301–796–4042, Deepika.Lakhani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:
I. Background

Upon request, FDA has classified the positive airway pressure delivery system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(f) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(f)(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and 21 CFR part 807 (21 U.S.C. 360k) and part 807, respectively.

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act (21 U.S.C. 360a(a)(1)). Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k) (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 14, 2017, FRESCA Medical submitted a request for De Novo classification of the CURVE™ Positive Airway Pressure System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on June 5, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 868.5273. We have named the generic type of device positive airway pressure delivery system, and it is identified as a prescription noninvasive ventilatory device that delivers expiratory positive airway pressure for patients suffering from obstructive sleep apnea. The system also provides positive airway pressure during incipient apnea. The system may include a dedicated flow generator and a patient interface.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

| TABLE 1—POSITIVE AIRWAY PRESSURE DELIVERY SYSTEM RISKS AND MITIGATION MEASURES |
|-----------------------------------------------|-------------------------------|
| Identified risks                              | Mitigation measures            |
| Adverse tissue reaction                       | Biocompatibility evaluation, and labeling. |
| Electromagnetic interference with other devices| Electromagnetic compatibility testing, and labeling. |
| Infection                                     | Reprocessing validation, and labeling. |
| Device software failure leading to ineffective treatment | Software verification, validation, and hazard analysis. |
| Device hardware failure/malfunction leading to high airway pressure, carbon dioxide rebreathing or ineffective treatment | Non-clinical performance testing, and labeling. |
| Electrical shock injury or thermal injury      | Electrical safety, thermal safety, and mechanical testing; Software verification, validation, and hazard analysis; and labeling. |
| Use error leading to ineffective therapy or patient injury | Labeling. |
FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, positive airway pressure delivery systems are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collection of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in part 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 868

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, part 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

§ 868.5273 Positive airway pressure delivery system.

(a) Identification. A positive airway pressure delivery system is a prescription noninvasive ventilatory device that delivers expiratory positive airway pressure for patients suffering from obstructive sleep apnea. The system also provides positive airway pressure during incipient apnea. The system may include a dedicated flow generator and a patient interface.

(b) Classification. Class II (special controls). The special controls for this device are:

1. The authority citation for part 868 continues to read as follows:


2. Add § 868.5273 to subpart F to read as follows:

§ 868.5273 Positive airway pressure delivery system.

(a) Identification. A positive airway pressure delivery system is a prescription noninvasive ventilatory device that delivers expiratory positive airway pressure for patients suffering from obstructive sleep apnea. The system also provides positive airway pressure during incipient apnea. The system may include a dedicated flow generator and a patient interface.

(b) Classification. Class II (special controls). The special controls for this device are:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.

2. (i) Waveform testing must simulate breathing conditions and evaluate pressure and airflow response over a range and combination of high and low breath rates and tidal volumes.

(iii) Use life testing must demonstrate adequate device performance over the labeled use life of the device.

(iv) Carbon dioxide rebreathing testing must be performed.

(v) System flow rate, maximum expiratory pressure, inhalation pressure, and intra-mask static pressure testing must be performed.

(vi) Air bolus testing must demonstrate that the device can withstand worst-case scenario air pressures.

(vii) Maximum limited pressure testing of the flow generator in single fault condition must be performed.

2. Add § 868.5273 to subpart F to read as follows:

§ 868.5273 Positive airway pressure delivery system.

(a) Identification. A positive airway pressure delivery system is a prescription noninvasive ventilatory device that delivers expiratory positive airway pressure for patients suffering from obstructive sleep apnea. The system also provides positive airway pressure during incipient apnea. The system may include a dedicated flow generator and a patient interface.

(b) Classification. Class II (special controls). The special controls for this device are:

1. The patient-contacting components of the device must be demonstrated to be biocompatible.

2. (i) Waveform testing must simulate breathing conditions and evaluate pressure and airflow response over a range and combination of high and low breath rates and tidal volumes.

(iii) Use life testing must demonstrate adequate device performance over the labeled use life of the device.

(iv) Carbon dioxide rebreathing testing must be performed.

(v) System flow rate, maximum expiratory pressure, inhalation pressure, and intra-mask static pressure testing must be performed.

(vi) Air bolus testing must demonstrate that the device can withstand worst-case scenario air pressures.

(vii) Maximum limited pressure testing of the flow generator in single fault condition must be performed.

3. Performance data must validate reprocessing instructions for any reusable components of the device.

4. Performance data must demonstrate the electrical, thermal, and mechanical safety and the electromagnetic compatibility of the device.

5. Software verification, validation, and hazard analysis must be performed.

6. Labeling must include the following:

(i) Therapy pressure range;

(ii) Use life replacement schedule for all components;

(iii) Cleaning instructions; and

(iv) Instructions for assembly and connection of device components.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–22840 Filed 10–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2018–N–3696]

Medical Devices; General and Plastic Surgery Devices; Classification of the Wound Autofluorescence Imaging Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the wound autofluorescence imaging device into class I. We are taking this action because we have determined that classifying the device into class I will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 19, 2018. The classification was applicable on July 31, 2018.


SUPPLEMENTARY INFORMATION:
I. Background

Upon request, FDA has classified the wound autofluorescence imaging device as class I (general controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(f) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360k) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)). Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). Although the device was automatically classified within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On February 16, 2018, MolecuLight, Inc. submitted a request for De Novo classification of the MolecuLight i:X. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class I if general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(A)). After review of the information submitted in the request, we determined that the device can be classified into class I. FDA has determined that general controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on July 31, 2018, FDA issued an order to the requester classifying the device into class I. FDA is codifying the classification of the device by adding 21 CFR 878.4165. We have named the generic type of device wound autofluorescence imaging device, and it is identified as a tool to view and diagnose wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.

FDA has identified the following risks to health associated specifically with this type of device: electrical/mechanical/thermal, electromagnetic compatibility (EMC) and optical safety of the device, and the error in fluorescence detection from the wound.

Section 510(j)(1) of the FD&C Act provides that a device within a type that has been classified into class I under section 513 of the FD&C Act is exempt from premarket notification under section 510(k), unless the device is of substantial importance in preventing impairment of human health or presents a potentially unreasonable risk of illness or injury (21 U.S.C. 360(j)(1)). Devices within this type are exempt from the premarket notification requirements under section 510(k), subject to the limitations of exemptions in 21 CFR 878.9.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820, regarding current good manufacturing practices, have been approved under OMB control number 0910–0073; and the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.
List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for part 878 continues to read as follows:


2. Add § 878.4165 to subpart E to read as follows:

§ 878.4165 Wound autofluorescence imaging device.

(a) Identification. A wound autofluorescence imaging device is a tool to view autofluorescence images from skin wounds that are exposed to an excitation light. The device is not intended to provide quantitative or diagnostic information.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9.


Leslie Kux,
Associate Commissioner for Policy.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the light based energy source device for topical applications class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(f) of the FD&C Act (21 U.S.C. 360c(f)(i)), and we may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360c(k) and part 807 (21 CFR part 807). FDA may also classify a device through the De Novo classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(ii)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application (PMA) to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

For this device, FDA issued an order on June 10, 2009, finding the ViruLite Cold Sore Machine not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On June 30, 2009, Pacer Therapeutics, Ltd., submitted a request for De Novo classification of the ViruLite Cold Sore Machine. FDA reviewed the request in
order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on October 18, 2012, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4860. We have named the generic type of device light based energy source device for topical application, and it is identified as a device that emits light energy at near infrared spectrum and is applied externally to the surface of herpes simplex labialis lesions on or around the lips.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Redness and discomfort</td>
<td>Clinical performance testing, Usability testing, and Labeling.</td>
</tr>
<tr>
<td>Burns and blisters</td>
<td>Clinical performance testing, Usability testing, and Labeling.</td>
</tr>
<tr>
<td>Adverse tissue reaction</td>
<td>Biocompatibility evaluation</td>
</tr>
<tr>
<td>Infection/transmissibility</td>
<td>Labeling, Cleaning and disinfection validation, and Usability testing.</td>
</tr>
<tr>
<td>Electrical shock</td>
<td>Electrical safety testing and Labeling.</td>
</tr>
<tr>
<td>Electromagnetic incompatibility</td>
<td>Electromagnetic compatibility testing and Labeling.</td>
</tr>
<tr>
<td>User error</td>
<td>Usability testing and Labeling.</td>
</tr>
<tr>
<td>Ocular injury</td>
<td>Labeling and Non-clinical performance testing for ocular safety.</td>
</tr>
</tbody>
</table>

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for part 878 continues to read as follows:


2. Add §878.4860 to subpart E to read as follows:

   §878.4860 Light based energy source device for topical application.
   (a) Identification. The device emits light energy at near infrared spectrum and is applied externally to the surface of herpes simplex labialis lesions on or around the lips.
   (b) Classification. Class II (special controls). The special controls for this device are:
   (1) The technical parameters of the device, including wavelength, treatment time, treatment area, energy density, spot size, and power, must be characterized.
   (2) The cleaning and disinfection instructions for the device must be validated.
   (3) The device must be demonstrated to be biocompatible.
   (4) Performance testing must validate electromagnetic compatibility (EMC), ocular safety, and electrical safety of the device.
   (5) Labeling must direct end-users to contact the device manufacturer and MedWatch if they experience any adverse events when using this device.
   (6) Labeling must include specific information pertinent to use of the device by the intended patient population and the treatment regimen.
   (7) Simulated use testing must include information from a usability, label comprehension and self-selection study to demonstrate that the device can be used by the intended patient population without any assistance.
   (8) Clinical data must show adequate reduction in time to healing and assess risks of redness, discomfort, burns, and blisters.
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 878
[Docket No. FDA–2018–N–3595]

SUPPLEMENTARY INFORMATION:

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the hemostatic device for intraluminal gastrointestinal use into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the hemostatic device for intraluminal gastrointestinal use’s classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 19, 2018. The classification was applicable on May 7, 2018.

FOR FURTHER INFORMATION CONTACT: Maegen Colehour, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G423, Silver Spring, MD, 20993–0002, 301–796–6436, Maegen.Colehour@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the hemostatic device for intraluminal gastrointestinal use as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(i)) and part 807 (21 CFR part 807). FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification at 21 CFR part 807 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(ii)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 9, 2017, Wilson-Cook Medical, Inc. submitted a request for De Novo classification of the Hemospray® Endoscopic Hemostat. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360a(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 7, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4456. We have named the generic type of device hemostatic device for intraluminal gastrointestinal use, and it is identified as a prescription device that is endoscopically applied to the upper and/or lower gastrointestinal tract and is intended to produce hemostasis via absorption of fluid or by other means.

FDA has identified the following risks to health associated specifically with this type of device and the measures
required to mitigate these risks in table 1.

### TABLE 1—HEMOSTATIC DEVICE FOR INTRALUMINAL GASTROINTESTINAL USE RISKS AND MITIGATION MEASURES

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bleeding:</strong></td>
<td></td>
</tr>
<tr>
<td>• Inability to achieve hemostasis</td>
<td>In vivo performance testing, Non-clinical performance testing, and Labeling.</td>
</tr>
<tr>
<td>• Recurrence of bleeding</td>
<td>Sterilization validation, Shelf life testing, and Labeling.</td>
</tr>
<tr>
<td><strong>Infection</strong></td>
<td>In vivo performance testing, Non-clinical performance testing, Biocompatibility evaluation, and Labeling.</td>
</tr>
<tr>
<td><strong>Adverse tissue reaction</strong></td>
<td>In vivo performance testing and Labeling.</td>
</tr>
<tr>
<td><strong>Obstruction of gastrointestinal (GI) tract</strong></td>
<td>In vivo performance testing and Labeling.</td>
</tr>
<tr>
<td><strong>GI distension or perforation</strong></td>
<td>In vivo performance testing and Labeling.</td>
</tr>
<tr>
<td><strong>Vascular obstruction:</strong></td>
<td>In vivo performance testing and Labeling.</td>
</tr>
<tr>
<td>• Ischemia</td>
<td>In vivo performance testing, Non-clinical performance testing, and Labeling.</td>
</tr>
<tr>
<td>• Emboli formation</td>
<td>In vivo performance testing and Labeling.</td>
</tr>
<tr>
<td><strong>Tissue trauma</strong></td>
<td>In vivo performance testing and Labeling.</td>
</tr>
<tr>
<td><strong>Improper device use</strong></td>
<td>In vivo performance testing and Labeling.</td>
</tr>
</tbody>
</table>

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, hemostatic devices for intraluminal gastrointestinal use are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

### III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820, regarding quality system regulations, have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

### List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

## PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for part 878 continues to read as follows:


2. Add § 878.4456 to subpart E to read as follows:

   § 878.4456 Hemostatic device for intraluminal gastrointestinal use.

   (a) Identification. A hemostatic device for intraluminal gastrointestinal use is a prescription device that is endoscopically applied to the upper and/or lower gastrointestinal tract and is intended to produce hemostasis via absorption of fluid or by other physical means.

   (b) Classification. Class II (special controls). The special controls for this device are:

   (1) The device must be demonstrated to be biocompatible.

   (2) Performance data must support the sterility and pyrogenicity of the device.

   (3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the identified shelf life.

   (4) In vivo performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The testing must evaluate the following:

   (i) The ability to deliver the hemostatic material to the bleeding site;

   (ii) The ability to achieve hemostasis in a clinically relevant model of gastrointestinal bleeding; and

   (iii) Safety endpoints, including thromboembolic events, local and systemic toxicity, tissue trauma, gastrointestinal tract obstruction, and bowel distension and perforation.

   (5) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

   (i) Materials characterization of all components must demonstrate the device meets established specifications, which must include compositional identity and purity, characterization of
I. Background

Upon request, FDA has classified the thermal vestibular stimulator for headache as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act.

Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)[B][I]). As a result, other device sponsors do not have to submit a De Novo request or premarket application to market a substantially equivalent device (see 21 U.S.C. 360c(f), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On April 18, 2017, Scion NeuroStim, LLC submitted a request for De Novo classification of the ThermoNeuroModulation Device. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)[B]). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 26, 2018, FDA issued an order to the requester classifying the device into class II.
is codifying the classification of the device by adding 21 CFR 882.5893. We have named the generic type of device thermal vestibular stimulator for headache, and it is identified as a prescription device used to stimulate the vestibular system by applying thermal waveforms through earpieces placed in a patient's ear canal for the treatment of headache.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

### Table 1—Thermal Vestibular Stimulator for Headache Risks and Mitigation Measures

<table>
<thead>
<tr>
<th>Adverse tissue reaction</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermal injury</td>
<td>Biocompatibility evaluation, Cleaning validation, and Labeling.</td>
</tr>
<tr>
<td>Ear tenderness and/or pruritus</td>
<td>Labeling, Non-clinical performance testing, Thermal safety testing, Technical specifications, and Software verification, validation, and hazard analysis.</td>
</tr>
<tr>
<td>Nausea and/or dizziness</td>
<td>Labeling, Non-clinical performance testing, and Thermal safety testing.</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>Labeling, Non-clinical performance testing, and Software verification, validation, and hazard analysis.</td>
</tr>
</tbody>
</table>

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, thermal vestibular stimulators for headache are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met

### III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820, regarding quality system regulations, have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

### List of Subjects in 21 CFR Part 882

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, part 882 is amended as follows:

#### PART 882—NEUROLOGICAL DEVICES

1. The authority citation for part 882 continues to read as follows:


2. Add §882.5893 to subpart F to read as follows:

   §882.5893 Thermal vestibular stimulator for headache.

   (a) Identification. The thermal vestibular stimulator for headache is a prescription device used to stimulate the vestibular system by applying thermal waveforms through earpieces placed in a patient’s ear canal for the treatment of headache.

   (b) Classification. Class II (special controls). The special controls for this device are:

   1. The patient-contacting components of the device must be demonstrated to be biocompatible.

   2. Performance testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety.

   3. The technical parameters of the device, including waveform outputs and temperature limits, must be identified.

   4. Cleaning validation of earpieces must be conducted.

   5. Software verification, validation, and hazard analysis must be performed.

   6. Labeling must include the following:

      i. Information on how the device operates and the typical sensations experienced during treatment;

      ii. A detailed summary of the device's technical parameters; and

      iii. Instructions for maintenance and cleaning of the device.


Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018–22842 Filed 10–18–18; 8:45 am]
classifying the intranasal electrostimulation device for dry eye symptoms into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the intranasal electrostimulation device for dry eye symptoms’ classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients’ access to beneficial innovative devices, in part by reducing regulatory burdens. DATES: This order is effective October 19, 2018. The classification was applicable on May 17, 2018.

FOR FURTHER INFORMATION CONTACT:
Elvin Ng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2431, Silver Spring, MD, 20993–0002, 240–402–4662, Elvin.Ng@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:
I. Background

Upon request, FDA has classified the intranasal electrostimulation device for dry eye symptoms as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as “postamendments devices” because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(i)) and part 807 (21 CFR part 807).

FDA may also classify a device through “De Novo” classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA shall classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k) (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining “substantial equivalence”). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On October 23, 2017, Allergan submitted a request for De Novo classification of the TrueTear Intranasal Tear Neurostimulator. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360a(1)[B]). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 17, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 886.5310. We have named the generic type of device intranasal electrostimulation device for dry eye symptoms, and it is identified as a prescription non-implantable, electrostimulation device intended to increase tear production for improvement in dry eye symptoms.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue damage due to overstimulation/understimulation or mechanical injury (ex: tips too long), device breakage.</td>
<td>Non-clinical performance testing; Software verification, validation, and hazard analysis; Electrical, thermal, and mechanical safety testing; and Labeling.</td>
</tr>
</tbody>
</table>
TABLE 1—INTRANASAL ELECTROSTIMULATION DEVICE FOR DRY EYE SYMPTOMS RISKS AND MITIGATION MEASURES—Continued

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse tissue reaction</td>
<td>Biocompatibility evaluation and Labeling.</td>
</tr>
<tr>
<td>Infection</td>
<td>Labeling.</td>
</tr>
<tr>
<td>Electrical shock or burn</td>
<td>Electrical, thermal, and mechanical safety testing;</td>
</tr>
<tr>
<td>Interference with other devices</td>
<td>Software verification, validation, and hazard analysis;</td>
</tr>
<tr>
<td>Pain, headache, or discomfort</td>
<td>and Labeling.</td>
</tr>
<tr>
<td>Failure to mitigate dry eye symptoms</td>
<td>Clinical performance testing; Non-clinical performance</td>
</tr>
<tr>
<td></td>
<td>testing; Electrical, thermal, and mechanical safety</td>
</tr>
<tr>
<td></td>
<td>testing; and Labeling.</td>
</tr>
</tbody>
</table>

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

At the time of classification, intranasal electrostimulation devices for dry eye symptoms are for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

III. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

1. The authority citation for part 886 continues to read as follows:


2. Add § 886.5310 to subpart F to read as follows:

§ 886.5310 Intranasal electrostimulation device for dry eye symptoms.

(a) Identification. An intranasal electrostimulation device for dry eye symptoms is a prescription non-implantable, electrostimulation device intended to increase tear production for improvement in dry eye symptoms.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must evaluate improvement of dry eye symptoms under anticipated conditions of use.

(2) Non-clinical performance testing must assess the following electrical output specifications: waveforms, output modes, maximum output voltage, maximum output current, pulse duration, frequency, net charge per pulse, maximum phase charge at 500 ohms, maximum current density, maximum average current, and maximum average power density.

(3) Patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance testing must demonstrate the electrical, thermal, and mechanical safety along with electromagnetic compatibility (EMC) of the device in the intended use environment.

(5) Software verification, validation, and hazard analysis must be performed.

(6) Training for the proper use of the device must be provided.

(7) Physician and patient labeling must include:

(i) Summaries of electrical stimulation parameters;

(ii) Instructions on how to correctly use and maintain the device;

(iii) Instructions and explanations of all user-interface components;

(iv) Information related to electromagnetic compatibility classification;

(v) Instructions on how to clean the device; and

(vi) Summaries of clinical performance testing demonstrating safety and effectiveness.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–22785 Filed 10–18–18; 8:45 am]

BILLING CODE 4164–01–P
DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0153]

Drawbridge Operation Regulation; Sacramento River, Sacramento, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Tower Drawbridge over the Sacramento River, mile 59.0, at Sacramento, CA. The deviation is necessary to allow the bridge owner to conduct mechanical and electrical rehabilitation work on the bridge. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

DATES: This deviation is effective without actual notice from October 19, 2018 through 6 a.m. on December 1, 2018. For the purposes of enforcement, actual notice will be used from 6 a.m. on October 8, 2018 until October 19, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0153, is available at http://www.regulations.gov. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District, telephone 206–220–7282, email d13-pf-d13bridges@uscg.mil.

SUPPLEMENTARY INFORMATION: On June 7, 2018, we published a temporary deviation entitled Drawbridge Operation Regulation; Willamette River at Portland, OR, in the Federal Register (83 FR 26364). That temporary deviation allowed Multnomah County to operate the subject bridge in single leaf, and reduce the vertical clearance from 7 a.m. on July 1, 2018 to 4 p.m. on October 13, 2018. While performing upgrades and repairs, the contracting company informed Multnomah County more time will be needed to complete the job. This modification is required to extend the authorized time so bridge work crews may complete bridge upgrades and repairs. Multnomah County owns and operates the Burnside Bridge. Multnomah County requested an extension to the current published temporary deviation, and is authorized to operate the Burnside Bridge in single leaf, and maintain the east leaf closed to marine vessels from 4 p.m. on October 13, 2018 to 4 p.m. on November 30, 2018.

The Burnside Bridge provides a vertical clearance of 41 feet in the closed-to-navigation position referenced to Columbia River Datum 0.0, and the east leaf will be reduced to 31 feet with scaffolding installed. The horizontal clearance for the west leaf opening will be 100 feet. The normal operating schedule is in 33 CFR 117.897. Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. The Coast Guard contacted all known users of the Willamette River for comment, and we received no objections for this deviation.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able to open for emergencies if at least 72-hour notice is given to the bridge operator. There is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterway through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.


Carl T. Hausner,
District Bridge Chief, Eleventh Coast Guard District.

[FR Doc. 2018–22746 Filed 10–18–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0300]

Drawbridge Operation Regulation; Willamette River at Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation; modification.

SUMMARY: The Coast Guard has modified a temporary deviation from the operating schedule that governs the Burnside Bridge across the Willamette River, mile 12.4, at Portland, OR. The deviation is necessary to accommodate bridge repairs and upgrades. This modified deviation extends the period the Burnside Bridge is authorized to operate in single leaf mode.

DATES: This deviation is effective without actual notice from October 19, 2018 to 4 p.m. on November 30, 2018. For purposes of enforcement, actual notice will be used from 4 p.m. on October 13, 2018, to October 19, 2018.

ADDRESSES: The docket for this deviation, USCG–2018–0300, is available at http://www.regulations.gov. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District, telephone 206–220–7282, email d13-pf-d13bridges@uscg.mil.

SUPPLEMENTARY INFORMATION: On June 7, 2018, we published a temporary deviation entitled Drawbridge Operation Regulation; Willamette River at Portland, OR, in the Federal Register (83 FR 26364). That temporary deviation allowed Multnomah County to operate the subject bridge in single leaf, and reduce the vertical clearance from 7 a.m. on July 1, 2018 to 4 p.m. on October 13, 2018. While performing upgrades and repairs, the contracting company informed Multnomah County more time will be needed to complete the job. This modification is required to extend the authorized time so bridge work crews may complete bridge upgrades and repairs. Multnomah County owns and operates the Burnside Bridge. Multnomah County requested an extension to the current published temporary deviation, and is authorized to operate the Burnside Bridge in single leaf, and maintain the east leaf closed to marine vessels from 4 p.m. on October 13, 2018 to 4 p.m. on November 30, 2018.

The Burnside Bridge provides a vertical clearance of 41 feet in the closed-to-navigation position referenced to Columbia River Datum 0.0, and the east leaf will be reduced to 31 feet with scaffolding installed. The horizontal clearance for the west leaf opening will be 100 feet. The normal operating schedule is in 33 CFR 117.897. Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. The Coast Guard contacted all known users of the Willamette River for comment, and we received no objections for this deviation.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able to open the west side of the span only for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will inform the users of the waterway, through our Local and Broadcast Notices to Mariners, of the change in operating schedule for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.
In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedules immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.


Steve M. Fischer, Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–22801 Filed 10–18–18; 8:45 am]
Mariners via VHF–FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard received no comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complaint about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting one hour that would prohibit entry within 500 feet of a fireworks barge. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under ADDRESSES.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the FOR FURTHER INFORMATION CONTACT section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:


2. Add § 165.T05–0711 to read as follows:

§ 165.T05–0711 Safety Zone; Delaware River; Penn’s Landing; Philadelphia, PA; Fireworks Display.

(a) Location. The following area is a safety zone: All waters of the Delaware River within a 500-foot radius of the fireworks barge, which will be anchored in approximate position 39°57’05.26” N Latitude 075°08’10.85” W Longitude. All coordinates are based on Datum NAD 1983.

(b) Definitions. As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard petty officer, warrant or commissioned officer on board a Coast Guard vessel or on board a federal, state, or local law enforcement vessel assisting the Captain of the Port, Delaware Bay in the enforcement of the safety zone.

(c) Regulations. (1) Under the general safety zone regulations in subpart C of this part—

(i) You may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP’s designated representative; and

(ii) All persons and vessels in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP’s designated representative.
IV. Discussion of the Rule

This rule establishes a temporary safety zone during the loading, staging, and transit of the fireworks barge, until after completion of the fireworks display. During the loading and staging of the pyrotechnics onto the fireworks barge, scheduled to take place from 11 a.m. to 8:30 p.m. on October 20, 2018, at Pier 50 in San Francisco, CA, the safety zone will encompass the navigable waters around and under the fireworks barge within a radius of 100 feet.

The fireworks barge will remain at Pier 50 until the start of its transit to the display location. Towing of the barge from Pier 50 to the display location is scheduled to take place from 8:30 p.m. to 9 p.m. on October 20, 2018, where it will remain until the conclusion of the fireworks display.

At 9 p.m. on October 20, 2018, 30 minutes prior to the commencement of the 10 minute fireworks display, the safety zone will increase in size and encompass the navigable waters around and under the fireworks barge within a radius of 420 feet in approximate position 37°48′15″N, 122°23′27″W (NAD 83) for the Hornblower Fireworks Display. The safety zone shall terminate at 10:10 p.m. on October 20, 2018.

The effect of the temporary safety zone is to restrict navigation in the vicinity of the fireworks loading, staging, transit, and firing site. Except for persons or vessels authorized by the COTP or the COTP’s designated representative, no person or vessel may enter or remain in the restricted areas. These regulations are needed to keep spectators and vessels away from the immediate vicinity of the fireworks firing sites to ensure the safety of participants, spectators, and transiting vessels.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant
regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the limited duration and narrowly tailored geographic area of the safety zone. Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified via public notice to Mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which may be small entities: owners and operators of waterfront facilities, commercial vessels, and pleasure craft engaged in recreational activities and sightseeing, if these facilities or vessels are in the vicinity of the safety zone at times when this zone is being enforced. This rule will not have a significant economic impact on a substantial number of small entities for the following reasons: (i) This rule will encompass only a small portion of the waterway for a limited period of time, and (ii) the maritime public will be advised in advance of these safety zones via Notice to Mariners.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132. Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000 or more (adjusted for inflation) or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone of limited size and duration. It is categorically excluded from further review under Categorical Exclusion L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under ADDRESSES.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the FOR FURTHER INFORMATION CONTACT section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:


2. Add § 165.T11–0847 to read as follows:

§ 165.T11–0847 Safety Zone; Hornblower Fireworks Display, San Francisco Bay, San Francisco, CA.

(a) Location. The following area is a safety zone: All navigable waters of the San Francisco Bay within 100 feet of the fireworks barge during loading and staging at Pier 50 in San Francisco, as well as transit and arrival to San Francisco, CA. From 11 a.m. on October
DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0910]

RIN 1625–AA00

Safety Zone; Fox River, Brown County Fireworks, Green Bay, WI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Fox River in Green Bay, WI, for all navigable waters within a 210-foot radius of the approximate launch position at 44°31′01.6″ N, 088°01′01.6″ W (NAD 83). This action is necessary to protect spectators, mariners, vessels, and property from potential hazards associated with a fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Lake Michigan or a designated representative.

DATES: This rule is effective from 7 p.m. through 7:30 p.m. on October 26, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, type USCG–2018–0910 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or email the marine event coordinator, MSTC Kaleena Carpino, Prevention Department, Coast Guard Sector Lake Michigan, Milwaukee, WI; telephone (414) 747–7148, email D09-SMB-SEClakeMichigan-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

<table>
<thead>
<tr>
<th>CFR</th>
<th>Code of Federal Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>DHS</td>
<td>Department of Homeland Security</td>
</tr>
<tr>
<td>FR</td>
<td>Federal Register</td>
</tr>
<tr>
<td>NPRM</td>
<td>Notice of proposed rulemaking</td>
</tr>
</tbody>
</table>

§ Section


II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. The final details for this event were not known to the Coast Guard until there was insufficient time remaining before the event to publish an NPRM. Delaying the effective date of this rule to wait for a comment period to run would be both impracticable and contrary to the public interest because it would inhibit the Coast Guard’s ability to protect the public, vessels, mariners, and property from the hazards associated with the fireworks display on October 26, 2018.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the Federal Register for the same reasons discussed in the preceding paragraph. Waiting for a 30 day notice period to run would be impracticable and contrary to the public interest.

III. Legal Authority and Need for Rule

The legal basis for this rule is the Coast Guard’s authority to establish safety zones: 33 U.S.C. 1231; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

The Coast Guard will enforce a safety zone on October 26, 2018, from 7 p.m. through 7:30 p.m., for a fireworks display on Fox River in Green Bay, WI. The Captain of the Port Lake Michigan has determined that this fireworks display will pose a significant risk to public safety and property. Such hazards include premature and accidental detonations, falling and burning debris, and collisions among spectator vessels.

IV. Discussion of the Rule

With the aforementioned hazards in mind, the Captain of the Port Lake Michigan has determined that this temporary safety zone is necessary to protect persons and vessels during the fireworks display in the waters of Fox River, in Green Bay, WI. This zone is effective and will be enforced from 7 p.m. through 7:30 p.m. on October 26, 2018. The safety zone will encompass all navigable waters of Fox River within a 210-foot radius of the approximate launch position at 44°31′01.6″ N, 088°01′01.6″ W (NAD 83).
Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan or a designated on-scene representative. The Captain of the Port or a designated on-scene representative may be contacted via VHF Channel 16.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. The safety zone created by this rule will be relatively small and enforced for only 30 minutes. Under certain conditions, vessels may still transit through the safety zone when permitted by the Captain of the Port. Moreover, the Coast Guard will issue Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, which might be small entities: The owners or operators of vessels intending to transit or anchor in the affected portion of Fox River, in Green Bay, WI between 7 p.m. through 7:30 p.m. on October 26, 2018. This safety zone will not have a significant economic impact on a substantial number of small entities for the reasons cited in the Regulatory Planning and Review section. Additionally, before the enforcement of the zone, we will issue local Broadcast Notice to Mariners and Public Notice of Safety Zone so vessel owners and operators can plan accordingly.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, 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. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a safety zone surrounding a fireworks display on Fox River, in Green Bay, WI. It is categorically excluded from further review under paragraph L(60[a]) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under ADDRESSES.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protestors. Protesters are asked to contact the person listed in the FOR FURTHER INFORMATION CONTACT section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52


Determination of Attainment by the Attainment Date and Clean Data Determination for the Logan, UT-ID 2006 24-Hour PM$_{2.5}$ Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing a determination of attainment by the attainment date and a clean data determination (CDD) for the 2006 24-hour fine particulate matter (PM$_{2.5}$) Logan, Utah (UT)-Idaho (ID) nonattainment area. These determinations are based upon quality-assured, quality-controlled and certified ambient air monitoring data for the period 2015–2017, available in the EPA’s Air Quality System (AQS) database, showing that the area has attained the 2006 24-hour PM$_{2.5}$ National Ambient Air Quality Standards (NAAQS). Based on the final determination that the Logan, UT-ID nonattainment area is currently attaining the 24-hour PM$_{2.5}$ NAAQS, the EPA is also issuing the final determination that the obligation for Utah and Idaho to make submissions to the Clean Air Act (CAA or the Act) requirements related to attainment of the NAAQS for this area is not applicable for as long as the area continues to attain the NAAQS.

DATES: This final rule is effective on October 19, 2018.

ADDRESSES: The EPA has established docket for this action under Docket ID No. EPA–RO8–OAR–2018–0309 and/or Docket ID No. EPA–R10–OAR–2018–0316. All documents in the docket are listed on the https://www.regulations.gov website. Although listed in the index, some information is not publicly available, e.g., 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 through http://www.regulations.gov, or please contact the person identified in the FOR FURTHER INFORMATION CONTACT section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Crystal Ostigaard, Air Program, EPA, Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. (303) 312–6602, ostigaard.crystal@epa.gov, or Matthew Jentgen, Air Planning Unit, Office of Air and Waste (OAW–150), EPA, Region 10, 1200 Sixth Avenue, Suite 900, Seattle, Washington 98101; (206) 553–0340; jentgen.matthew@epa.gov.

SUPPLEMENTARY INFORMATION: Throughout this document, wherever “we”, “us” or “our” is used, it is intended to refer to the EPA.

I. Background

On October 17, 2006 (71 FR 61144), the EPA revised the level of the 24-hour PM$_{2.5}$ NAAQS, lowering the primary and secondary standards from the 1997 standard of 65 micrograms per cubic meter (µg/m$^3$) to 35 µg/m$^3$. On November 13, 2009 (74 FR 56888), the EPA designated several areas as nonattainment for the 24-hour PM$_{2.5}$ NAAQS of 35 µg/m$^3$, including the Logan, Utah UT-ID nonattainment area.

On July 17, 2018 (83 FR 33886), the EPA proposed to determine, based on the most recent 3 years (2015–2017) of valid data, that the Logan, UT-ID nonattainment area has attained the 2006 primary and secondary 24-hour PM$_{2.5}$ NAAQS by the December 31, 2017 attainment date. In addition, based on the CDD, the EPA also proposed to determine that the obligation to submit any remaining attainment-related SIP revisions arising from classification of the Logan, UT-ID area as a Moderate nonattainment area under subpart 4 of part D (of title I of the Act) for the 2006 24-hour PM$_{2.5}$ NAAQS is not applicable so long as the area continues to attain the 2006 24-hour PM$_{2.5}$ NAAQS. Additional detail can be found in the Federal Register.

II. Response to Comments

The EPA received eight public comments on the proposed action. Three of the comments related to forestry practices and wildfire management, primarily in California. One comment related to child labor practices in South America. One comment related to homelessness in California. Another comment discussed

---

1 Meeting the requirements of 40 CFR part 50, appendix N, and part 58.
water quality issues in Venezuela. Finally, one comment raised issues concerning lead-based paint. None of these seven comments recommended that the EPA take a different action than the EPA proposed on July 17, 2018 (83 FR 33886). The eighth comment was received from the Idaho Conservation League (ICL) and raised issues relevant to this action, which are addressed below. After reviewing the comments received, the EPA has determined that the comments, with the exception of the ICL comment, fall outside the scope of our proposed action or fail to identify any material issue necessitating a response.

The ICL comment raises concerns regarding monitoring data trends at the Franklin, ID and, to a lesser extent, the Smithfield, UT sites. The comment states that the 3-year average (2015–2017) at the Franklin, ID monitoring site was 30 µg/m³; however, the 98th percentile rose each year (18.8, 33.3, and 38.3 µg/m³, respectively). The commenter briefly mentions the Smithfield, UT monitor and how the 98th percentiles for the three years (2015–2017) rose too, but to a lesser extent. The comment also asserts that if the 2016 monitoring data at the Franklin, ID site yields a 98th percentile measurement of greater than 33.4 µg/m³ (the commenter observes that this measurement is not unreasonable for this site), then the 2016–2018 design value would exceed the standard of 35 µg/m³. The commenter requests that the EPA addresses why the year-to-year increases in PM₂.₅ is occurring, and what regulatory measures are in place to prevent this area from violating again.

In accordance with section 188(b)(2) of the CAA, the EPA is required to determine within 6 months of the applicable attainment date whether a nonattainment area attained the standard by that date. On September 8, 2017, the EPA extended the attainment date for the Logan, UT-ID PM₂.₅ nonattainment area to December 31, 2017, upon which the EPA proposed a determination of attainment. A determination of attainment is not equivalent to a redesignation, and the states must still meet the statutory requirements for redesignation in order for the area to be redesignated to attainment. The comment may be referring to a redesignation rather than a determination that the area attained by the attainment date and/or a CDD, so the EPA reiterates that the designation status of the area will remain nonattainment for the 2006 PM₂.₅ NAAQS, until such time as the EPA determines that the area meets the CAA requirements for redesignation to attainment in CAA section 107(d)(3)(E).

The EPA has established regulations for determining if the 24-hour PM₂.₅ NAAQS has been met at 40 CFR 50.13 and part 50, appendix N, section 4.2. Specifically, under 40 CFR 50.13 and part 50, appendix N, section 4.2, the 2006 24-hour PM₂.₅ NAAQS is met when the 24-hour PM₂.₅ NAAQS design value at each eligible monitoring site is less than or equal to 35 µg/m³. Three years of valid annual PM₂.₅ 98th percentile mass concentrations generally are required to produce a valid design value. The regulations do not require that there be a downward trend over the course of the three years used to calculate the design value. Rather, according to part 50, appendix N, section 4.5, the design value is an average of the three years of valid annual PM₂.₅ 98th percentile mass concentrations. Thus, the process the EPA uses to calculate a design value accounts for the fluctuations in 98th percentiles at the Logan, UT and Smithfield, UT monitoring sites. Following the requirements of 40 CFR 50.13 and part 50, appendix N, the EPA determined that the design values at both the Smithfield, UT and Franklin, ID monitors are below 35 µg/m³, thus the proposed determination of attainment by the attainment date and the proposed CDD are appropriate. Also, the 3-year design values are lower for the time period used for this attainment determination compared to the time period when the area was designated nonattainment. The Logan, UT design value used for designations was 36 µg/m³ (2006–2008). The first period when both the Logan, UT and Franklin, ID monitors had valid design values was in 2008–2010, when the Logan, UT monitor recorded a PM₂.₅ 24-hour concentration of 43 µg/m³ and the Franklin, ID monitor was 46 µg/m³. In comparison, the most recent design value (2015–2017) is 33 µg/m³ for the Logan, UT monitor and 30 µg/m³ for the Franklin, ID monitor, which shows attainment. Moreover, since being designated as a Moderate nonattainment area in 2009, Utah and Idaho have adopted and implemented reasonably available control measures (RACM), including reasonably available control technologies (RACT), on sources of direct PM₂.₅ and PM₁₀ precursors. Based on the overall trend towards attainment since the area was designated as nonattainment in 2009, as well as the implementation of RACM on sources in the nonattainment area, it is unlikely that re-violate the 24-hour PM₂.₅ NAAQS. Furthermore, as described in detail in our proposal notice, should the area subsequently violate the 24-hour PM₂.₅ NAAQS, in accordance with 40 CFR 51.1015(a)(2), the EPA would rescind the CDD, and Utah and Idaho would be obligated to submit a SIP revision to address any deficiencies. Therefore, the EPA is finalizing our action as proposed.

III. Final Action

Pursuant to CAA section 188(b)(2), the EPA is finalizing a determination, based on the most recent 3 years (2015–2017) of valid data, that the Logan, UT-ID nonattainment area has attained the 2006 primary and secondary 24-hour PM₂.₅ NAAQS by the December 31, 2017 attainment date.

In addition, the EPA is finalizing a determination that the obligation to submit any remaining attainment-related SIP revisions arising from classification of the Logan, UT-ID area as a Moderate nonattainment area under subpart 4 of part D (of title I of the Act) for the 2006 24-hour PM₂.₅ NAAQS is not applicable under the Clean Data Policy for so long as the area continues to attain the 2006 24-hour PM₂.₅ NAAQS. See 40 CFR 51.1015(a). In particular, the obligation for Utah and Idaho to submit attainment demonstrations, projected emissions inventories, RACM (including RACT), reasonable further progress (RFP) plans, motor vehicle emissions budgets (MVEB), quantitative milestones, and contingency measures, for the Logan, UT-ID area are suspended until such time as: (1) The area is redesignated to attainment, after which such requirements are permanently discharged; or (2) The EPA determines that the area has re-violated the PM₂.₅ NAAQS, at which time the state shall submit such attainment plan elements for the Moderate nonattainment area by a future date to be determined by the EPA and announced through publication in the Federal Register at the time the EPA determines the area is violating the PM₂.₅ NAAQS.

As discussed in the 2015 PM₂.₅ SIP Requirements Rule, the nonattainment base emissions inventory required by section 172(c)(3) is not suspended by this determination because the base inventory is a requirement independent of planning for an area’s attainment. See 81 FR 58009 at 58028 and 58127–9; 80 FR 15340 at 15441–2. Additionally, Nonattainment New Source Review

²On August 24, 2016, the EPA finalized the Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements ("PM₁₀ SIP Requirements Rule"), 81 FR 58010.
(NNSR) requirements are discussed in the PM\textsubscript{2.5} SIP Requirements Rule, and required by CAA sections 110(a)(2)(C); 172(c)(5); 173; 189(a); and 189(e), and are not being suspended by a CDD because this requirement is independent of the area’s attainment planning. See 81 FR 58010 at 58107 and 58127.

This determination does not invalidate any prior actions that the EPA has made on any Moderate PM\textsubscript{2.5} area attainment plan elements that were submitted by either the State of Utah or the State of Idaho for the Logan, UT-ID Moderate PM\textsubscript{2.5} area attainment plans. This action does not preclude either state from submitting, nor the EPA from acting on, the suspended attainment plan elements. As a result of this final action, the sanctions and Federal Implementation Plan (FIP) clocks triggered by the partial disapproval of the contingency measure element of the Idaho portion of the Logan, UT-ID PM\textsubscript{2.5} SIP are suspended.

This final action does not constitute a redesignation of the Logan, UT-ID nonattainment area to attainment for the 2006 24-hour PM\textsubscript{2.5} NAAQS under CAA section 107(d)(3) because we have not yet approved a maintenance plan for Logan, UT-ID as meeting the requirements of section 175A of the CAA or determined that the area has met the other CAA requirements for redesignation. The classification and designation status in 40 CFR part 81 remains Moderate nonattainment for this area until such time as the EPA determines that Utah and Idaho have met the CAA requirements for redesignation to attainment for the Logan, UT-ID nonattainment area.

In accordance with 5 U.S.C. 553(d), the EPA finds there is good cause for these determinations to become effective immediately upon publication in the Federal Register. The expedited effective date for these actions is authorized under both 5 U.S.C. 553(d)(1), which provides that rule actions may become effective less than 30 days after publication if the rule “grants or recognizes an exemption or relieves a restriction,” and 5 U.S.C. 553(d)(3), which allows an effective date less than 30 days after publication “as otherwise provided by the agency for good cause found and published with the rule.” As noted above, this determination of attainment will result in a suspension of the requirements for Idaho and Utah to submit attainment demonstrations, projected emissions inventories, RACM (including RACT), RFP plans, MVEB, quantitative milestones, and contingency measures, so long as the Logan, UT-ID area continues to attain the PM\textsubscript{2.5} NAAQS. Furthermore, the sanctions and FIP clocks triggered by the partial disapproval of the contingency measure element of the Idaho portion of the Logan, UT-ID PM\textsubscript{2.5} SIP are suspended. The suspension of these requirements and the suspension of sanctions is sufficient reason to allow an expedited effective date of this rule under 5 U.S.C. 553(d)(1). In addition, the suspension of the obligations of Idaho and Utah to make submissions for these requirements provides good cause to make this rule effective on the date of publication of this action in the Federal Register, pursuant to 5 U.S.C. 553(d)(3). The purpose of the 30-day waiting period prescribed in 5 U.S.C. 553(d) is to give affected parties a reasonable time to adjust their behavior and prepare before the final rule takes effect. Where, as here, the final rule suspends requirements rather than imposes obligations, affected parties, such as Idaho and Utah, do not need time to adjust and prepare before the rule takes effect.

IV. Statutory and Executive Order Reviews

This action finalizes a determination of attainment based on air quality and suspends certain federal requirements, and thus would not impose additional requirements beyond those imposed by state law. For this reason, this final 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);
- Is not expected to be an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because this action is not significant under Executive Order 12866;
- 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); and
- 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 26355, May 22, 2001); and
- Is not subject to requirements of Section 2(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 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).

In addition, 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 December 18, 2018. 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, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 et seq.  
Dated: September 27, 2018.

Douglas B. Benevento,  
Regional Administrator, Region 8.  
Dated: September 27, 2018.

Chris Hladick,  
Regional Administrator, Region 10.  
[FR Doc. 2018–22284 Filed 10–18–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180  
Prothioconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of prothioconazole in or on rapeseed subgroup 20A. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 19, 2018. Objections and requests for hearings must be received on or before December 18, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0531, is available at http://www.regulations.gov or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Blvd., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. 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 OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (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.

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 211).  
• Pesticide manufacturing (NAICS code 23532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Publishing Office’s e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0531 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before December 18, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket.

Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0531, 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 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 http://www.epa.gov/dockets.

II. Summary of Petitioned-For Tolerance

In the Federal Register of February 27, 2018 (83 FR 8408) (FRL–9972–17), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7F8596) by Bayer CropScience, LP2, T.W. Alexander Dr., Research Triangle Park, NC 27709. The petition requested that 40 CFR 180.226 be amended by establishing tolerances for residues of the fungicide prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H–1,2,4-triazole-3-thione, and its desthiobiotetin in or on rapeseed subgroup, Crop subgroup 20A at 0.15 parts per million (ppm). That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, http://www.regulations.gov. Comments were received on the notice of filing. EPA’s response to those comments is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing the tolerance requested by the petitioner as Rapeseed subgroup 20A, to be consistent with the commodity terminology commonly used by the Agency.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the
legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children as aggregate exposure to the pesticide chemical residue. . . .”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of, and to make a determination on aggregate exposure for prothioconazole including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with prothioconazole follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Prothioconazole degrades into different compounds in different matrices, with prothioconazole-desthio (desthio) being the metabolite and degrade of concern. The target organs of prothioconazole and the desthio metabolite include the liver, kidney, bladder, thyroid, and blood. In addition, the chronic studies showed body weight and food consumption changes, and toxicity to the lymphatic and gastrointestinal systems.

Developmental studies show that prothioconazole and its metabolites produce adverse effects including malformations in the conceptus at levels equal to or below maternally toxic levels. Pregnancy studies conducted using prothioconazole-desthio suggest that these chemicals do not adversely affect reproductive parameters or the offspring except at parentally toxic dose levels. Acute and subchronic neurotoxicity studies, as well as a developmental neurotoxicity study, raise no neurotoxicity concerns. Immunotoxicity data show that prothioconazole is not an immunotoxicant.

The available carcinogenicity and/or chronic studies in the mouse and rat, using both prothioconazole and prothioconazole-desthio, show no increase in tumor incidence and EPA has concluded that prothioconazole and its metabolites are not carcinogenic.

Specific information on the studies received and the nature of the adverse effects caused by prothioconazole as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://www.regulations.gov in the document titled “Prothioconazole: Human Health Risk Assessment for a Proposed Tolerance on Cottonseed Subgroup 20C, a Tolerance Amendment on Sugar Beet Roots, and New Use Requests for Cotton, Sugar Beet, Soybean, and Dried Shelled Pea and Bean” on page 32 in docket ID number EPA–HQS–OPP–2015–0722.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see http://www.epa.gov/pesticides/factsheets/riskassess.html.

A summary of the toxicological endpoints for prothioconazole used for human risk assessment is discussed in Unit III.B of the final rule published in the Federal Register of November 10, 2016 (81 FR 78917) (FRL–9953–71).

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to prothioconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing prothioconazole tolerances in 40 CFR 180.626. EPA assessed dietary exposures from prothioconazole in food as follows:

i. Acute exposure. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for prothioconazole for females 13–50 years old. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA; 2003–2008). As to residue levels in food, EPA assumed tolerance-level values for the proposed new uses and existing tolerances on berries, cucurbit vegetables, cottonseed, sugar beet roots, and sunflower subgroup 20B, average field trial residues for all other commodities, and DEEM default and empirical processing factors. 100 percent crop treated (PCT) was assumed for all proposed and established commodities.

ii. Chronic exposure. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA; 2003–2008. As to residue levels in food, EPA assumed tolerance-level values for the proposed new uses and existing tolerances on berries, cucurbit vegetables, cottonseed, sugar beet roots, and sunflower subgroup 20B, average field trial residues for all other commodities, and DEEM default and empirical processing factors. 100 PCT was assumed for all proposed and established commodities.

iii. Cancer. Based on the data summarized in Unit III.A., EPA has concluded that prothioconazole does not pose a cancer risk to humans. Therefore, a dietary exposure
assessment for the purpose of assessing cancer risk is unnecessary.

iv. Anticipated residue information.
Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

The Agency did not use percent crop treated estimates for the dietary assessment.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for prothioconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of prothioconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM/GW), the estimated drinking water concentrations (EDWCs) of prothioconazole for acute exposures are estimated to be 109 parts per billion (ppb) for surface water and 128 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 132 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration value of 128 ppb was used to assess the contribution to drinking water.

3. From non-dietary exposure. The term “residential exposure” is used in this document to refer to non-occupational dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termite control, and flea and tick control on pets). Prothioconazole is not registered for any specific use patterns that would result in residential exposure.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(DI)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

Prothioconazole is a member of the conazole class of pesticides containing the 1,2,4-triazole moiety. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events in mammals (EPA, 2002). In the case of conazoles, however, a variable pattern of toxicological responses is found. Some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no conclusive data to indicate that conazoles share common mechanisms of toxicity, and EPA is not following a cumulative risk approach for this the conazoles. For information regarding EPA’s procedures for cumulating effects from substances found to have a common mechanism of toxicity, see EPA’s website at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.

Prothioconazole is a triazole-derived pesticide. This class of compounds can form the common metabolite 1,2,4-triazole and two triazole conjugates (triazolylalanine and triazolylacetic acid). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, including prothioconazole, EPA conducted a human health risk assessment for exposure to 1,2,4-triazole, triazolylalanine, and triazolylacetic acid resulting from the use of all current and pending uses of any triazole-derived fungicide. The risk assessment is a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (e.g., use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (i.e., high end estimates of both dietary and non-dietary exposures). The Agency retained a 3X for the LOAEL to NOAEL safety factor when the reproduction study was used. In addition, the Agency retained a 10X for the lack of studies including a developmental neurotoxicity (DNT) study. The assessment includes evaluations of risks for various subgroups, including those comprised of infants and children. The Agency’s complete risk assessment is found in the propiconazole reregistration docket at http://www.regulations.gov, Docket Identification (ID) Number EPA–HQ–OPP–2005–0497.

An updated dietary exposure and risk analysis for the common triazole metabolites 1,2,4-triazole (T), triazolylalanine (TA), triazolylacetic acid (TAA), and triazolylpyruvic acid (TP) was completed on July 18, 2017, in association with registration requests for the triazole fungicides difenoconazole and tetraconazole. That analysis concluded that risk estimates were below the Agency’s level of concern for all population groups. The proposed new uses of prothioconazole are not expected to significantly increase the dietary exposure estimates for free triazole or conjugated triazoles; thus, the Agency is relying on the July 18, 2017 analysis to support its conclusion that the exposure to the triazole metabolite, including exposures from the use of prothioconazole on the commodities in subgroup 20A, does not present risks of concern. This assessment may be found on http://www.regulations.gov by searching for the following title and docket number: “Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address New Section 3 Registrations for Use of Difenoconazole and Tetraconazole,” (located in docket ID number EPA–HQ–OPP–2016–0254).

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different
margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. Prenatal and postnatal sensitivity.

There are adequate data in the prothioconazole/prothioconazole-desthio toxicological database to characterize the potential for pre-natal or post-natal risks to infants and children: Two-Generation reproduction studies in rats; developmental studies in rats and rabbits; and a DNT study in rats. The effects seen in these studies suggest that offspring are more susceptible. Offspring adverse effects were seen at levels below the LOAELs for maternal toxicity and, in general, were of comparable or greater severity compared to the effects observed in adults. However, clear NOAELs are established for offspring and fetal effects. The most sensitive effects (malformed vertebral body and ribs, anthropyrosis, and other multiple malformations) seen in the fetuses of a rabbit developmental study are established as the toxicity endpoints with a POD of 2 mg/kg/day. This POD is protective all fetal and offspring effects seen in the developmental toxicity and developmental neurotoxicity studies.

3. Conclusion. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for prothioconazole is complete.

ii. No neurotoxicity was seen in acute and subchronic neurotoxicity studies and other studies with prothioconazole or prothioconazole-desthio. Although offspring neurotoxicity was found, characterized by peripheral nerve lesions in the developmental neurotoxicity study on prothioconazole-desthio, the increase was seen only in the highest dose group at 105 mg/kg/day. Further, a NOAEL was established for the peripheral nerve lesions and all of the PODs used in the risk assessment were protective of this finding.

iii. Evidence of quantitative and qualitative susceptibility of offspring were observed in the developmental studies. However, basing the POD on the offspring in the most sensitive of these studies provides the needed protection of offspring.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues for the proposed new uses and existing tolerances on berries, cucurbit vegetables, cottonseed, sugar beet roots, and sunflower subgroup 20B, average field trial residue levels for the remaining uses, and DEEM default and empirical processing factors. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to prothioconazole in drinking water. These assessments will not underestimate the exposure and risks posed by prothioconazole.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. Acute risk. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to prothioconazole will occupy 40% of the aPAD for females 13–49 years old, the population group receiving the greatest exposure.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to prothioconazole from food and water will utilize 77% of the cPAD for all infants less than 1-year-old the population group receiving the greatest exposure. There are no residential uses for prothioconazole.


Both short- and intermediate-term adverse effects were identified; however, prothioconazole is not registered for any uses patterns that would result in either short- or intermediate-term residential exposure. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposure plus chronic dietary exposure. Because there is no short- or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for prothioconazole.

4. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, prothioconazole is not expected to pose a cancer risk to humans.

5. Determination of safety. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to prothioconazole residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate liquid chromatography with tandem mass spectrometry (LC/MS/MS) methods are available for enforcing prothioconazole tolerances in crop and livestock commodities. The method may be requested from:

Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: residuemetods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRL for prothioconazole in or on rapeseed at 0.1 ppm. The MRL is different than the...
tolerance established for prothioconazole in the United States. The residues of concern are not harmonized between the U.S. and Codex, since Codex only includes prothioconazole-desthioc, whereas the U.S. includes prothioconazole parent as well as prothioconazole-desthioc, and harmonization may result in tolerance exceedances from use in accordance with the label.

C. Response to Comments

Two comments were submitted in response to the Notice of Filing for tolerance expansion. One comment (Comment A) requested that EPA deny this tolerance petition based on the radioactivity of prothioconazole and its role as a developmental toxicant. The other comment (Comment B) requested that EPA deny this petition based on the persistence of prothioconazole in the digestive system and effects on the liver, kidney, and thyroid.

In response to Comment A, prothioconazole is not radioactive. In some studies, the prothioconazole is radio-labeled in order to track how the chemical moves through the body of an organism after consumption, but prothioconazole itself is not radioactive. Although evidence of quantitative and qualitative susceptibility of offspring was observed in the developmental studies in rats and rabbits including the developmental neurotoxicity study; points of departure (PODs) are based on the most sensitive endpoints in the fetuses of the rabbit developmental study; therefore, the risk assessment is protective of any developmental effects of this chemical.

In response to Comment B, the effect of persistence and/or bioaccumulation on the toxicity of a chemical is evaluated in the repeated dose studies. For example, the severity of adverse effects and the relative dose levels at which they occur can be compared in a subchronic study versus a chronic study in the case of prothioconazole, a comparison of the subchronic (90-day) study in the rat with the chronic (2-year) studies in the rat, using data on both the parent compound and the desthi metabolite, shows there is no basis for concern for potential persistence, because the PODs are not significantly different in the two time-periods. The same is true among the generations in the reproduction and fertility study where the subsequent generations are not shown to be more sensitive to prothioconazole toxicity than the first generation. The rat studies are referred to here because the metabolism studies which would show persistence and/or bioaccumulation were conducted in the rat. If a basis for concern were demonstrated in the toxicity database the PODs, which are based on the most sensitive endpoints, would be protective of this effect. The target organs of prothioconazole and the desthi metabolite include the liver, kidney, bladder, thyroid and blood. The risk assessment uses the most sensitive endpoints to set PODs, so the assessment is protective of all effects to the liver, kidney, and thyroid.

V. Conclusion

Therefore, tolerances are established for residues of prothioconazole, 2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione, and its desthi metabolite, in or on rapeseed subgroup 20A at 0.15 ppm. In addition, EPA is removing the existing tolerance for “rapeseed, seed” as it is superseded by the new tolerance for subgroup 20A.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCRA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19985, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it 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).

Since tolerances and exemptions that are established on the basis of a petition under FFDCRA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not 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. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), EPA will submit a report containing this rule 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. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 11, 2018.

Daniel Rosenblatt,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:
§ 180.626 Prothioconazole; tolerances for residues.

(a) * * *

(b) Add alphabetically “Rapeseed subgroup 20A” to the table in paragraph (a)(1).

The addition reads as follows:

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapeseed subgroup 20A</td>
<td>0.15</td>
</tr>
</tbody>
</table>

[FR Doc. 2018–22857 Filed 10–18–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180


Boscalid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of boscalid in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 19, 2018. Objections and requests for hearings must be received on or before December 18, 2018, and requests for hearing must be filed in accordance with the instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute. Such information should be submitted in writing, and must be in writing, and must be identified as confidential business information (CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0310, by one of the following methods:

- Fax: (202) 566–0253.

II. Summary of Petitioned–For Tolerance

In the Federal Register of October 23, 2017 (82 FR 49020) (FRL–9967–37), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8564) by IR–4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.589 be amended by establishing tolerances for residues of the fungicide boscalid, 3-pyridinecarboxamide, 2-chloro-N′-(4′- chloro[1′-biphenyl]-2-y1) in or on Brassica leafy greens subgroup 4–16B at 50 parts per million; celtuce at 45 ppm; Florence, fennel at 45 ppm; kohlrabi at 6 ppm; leaf petiole vegetable subgroup 22B at 45 ppm; leafy greens subgroup 4–16A at 70 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 2.5 ppm; pea and bean, succulent shelled, subgroup 6B at 0.6 ppm; vegetable, Brassica head and stem group 5–16 at 6 ppm; vegetable, cucurbit group 9 at 3 ppm; and vegetable root, except sugar beet, subgroup 1B at 2.0 ppm. The petition also requested the removal of the established tolerances for boscalid in or on Brassica, head and stem, subgroup 5A at 3.0 ppm, Brassica,
leaky greens, subgroup 5B at 18 ppm, cucumber at 0.5 ppm, leaf petioles subgroup 4B at 45 ppm; leafy greens subgroup 4A, except head lettuce and leaf lettuce at 60 ppm, lettuce, head at 6.5 ppm, lettuce, leaf at 11 ppm, pea and bean, dried shelled, except soybean, subgroup 6C, except cowpea, field pea and grain lupin at 2.5 ppm; pea and bean, succulent shelled, subgroup 6B, except cowpea at 0.6 ppm; turnip, greens at 40 ppm, vegetable, cucurbit group 9, except cucumber at 1.6 ppm, and vegetable, root, subgroup 1A, except sugar beet, garden beet, radish and turnip at 1.0 ppm and the removal of the established tolerances for indirect or inadvertent residues of boscalid, in or on beet, garden, roots at 0.1 ppm; cowpea, seed at 0.1 ppm; lupin, grain, grain at 0.1 ppm; pea, field, seed at 0.1 ppm; radish, roots at 0.1 ppm; and turnip, roots at 0.1 ppm. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket, http://www.regulations.gov. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which some of the tolerances are being established. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for boscalid including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with boscalid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

In mammals, the target organs are the liver and the thyroid (indirectly from liver adaptive response). In subchronic and chronic feeding studies in rats, mice and dogs, boscalid generally caused decreased body weights (primarily in mice) and effects on the liver (increases in weights, changes in enzyme levels and histopathological changes) as well as on the thyroid (increase in weights and histopathological changes). Mode of action studies conducted in rats indicated that boscalid has a direct effect upon the liver and that the thyroid effects are secondary. A reversibility study in rats indicated that both liver and thyroid parameters returned to control values after the animals were placed on control diet. Absolute and/or relative thyroid weights were elevated in rats and dogs, but there were no histopathological changes observed in the thyroid in either mice or dogs.

In a developmental toxicity study in rats, no developmental toxicity was observed in the fetuses at the highest dose tested (limit dose). No effects were noted in the dams in this study. In a developmental toxicity study in rabbits, an increased incidence of abortions or early delivery was observed at the limit dose. There was quantitative evidence of increased susceptibility in the two-generation reproduction study in rats, where decreases in body weights in male offspring were seen at a dose that was lower than the dose that induced parental/systemic toxicity. There was quantitative evidence of increased susceptibility in the developmental neurotoxicity study in rats, where decreases in pup body weights on postnatal day four (PND 4) and body weight gains (PND 1–4) were seen in the absence of any maternal toxicity.

In a 2-year chronic toxicity study and a 2-year chronic study in male and female rats, the combined data showed an increased trend in thyroid follicular cell adenomas that appeared to be treatment-related in males. This was supported by thyroid hypertrophy and hyperplasia of follicular cells at the same dose as well as increased thyroid weights plus mechanistic data. Despite these findings, the Agency has determined that quantification of the cancer risk is not necessary because (1) the adenomas occurred at dose levels above the level used to establish the chronic population adjusted dose (cPAD); (2) statistically significant increases were only seen for benign tumors (adenomas) and not for malignant ones (carcinomas); (3) the increase in adenomas in females was slight; and (4) there was no evidence of mutagenicity. Furthermore, the mouse carcinogenicity study was negative.

There was no evidence of neurotoxicity in rats in the acute, subchronic or developmental studies up to the limit dose. No neurotoxic observations were noted in any of the other studies in any species. Similarly, there was no evidence of immunotoxicity in the available immunotoxicity study in rats, or in any of the other studies in the database.

Specific information on the studies received and the nature of the adverse effects caused by boscalid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://www.regulations.gov on pages 35–40 of the document titled “Boscalid, Human Health Risk Assessment of Tolerance Requests for Brassica, Leafy Greens, Subgroup 4–16B; Celuce; Florence Fennel; Kohlrabi; Leaf Petiole Vegetable Subgroup 22B; Leafy Greens Subgroup 4–16A; Pea and Bean, Dried Shelled, Except Soybean, Subgroup 6C; Pea and Bean, Succulent Shelled, Subgroup 6B; Vegetable, Brassica, Head and Stem, Group 5–16, Vegetable, Cucurbit, Group 9; and Vegetable, Root, Except Sugar Beet, Subgroup 1B; and Associated Registration Requests on Greenhouse-grown Fruiting Vegetables, Cucurbit Vegetables, and Leafy Vegetables” in docket ID number EPA–HQ–OPP–2017–0310.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the POD is used as the basis for derivation of reference values for risk assessment.
PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RFD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-risk-assessment.

A summary of the toxicological endpoints for boscalid used for human risk assessment is discussed in Unit III.B. of the final rule published in the Federal Register of November 8, 2013 (78 FR 67042) (FRL—9401–5).

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to boscalid, EPA considered exposure under the petitioned-for tolerances as well as all existing boscalid tolerances in 40 CFR 180.589. EPA assessed dietary exposures from boscalid in food as follows:

i. Acute exposure. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for boscalid; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. Chronic exposure. In conducting the chronic dietary exposure assessment EPA used food consumption information from the 2003–2008 food consumption data from the U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance-level residues and 100 percent crop treated (PCT).

iii. Cancer. EPA has concluded that the chronic endpoint will be protective of potential cancer effects. EPA’s estimate of chronic exposure as described above is relied upon to evaluate whether any exposure could exceed the chronic population adjusted doses (cPAD) and thus pose a cancer risk. iv. Anticipated residue and PCT information. EPA did not use anticipated residue or PCT information in the dietary assessment for boscalid. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. Dietary exposure from drinking water. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for boscalid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of boscalid. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) model and Pesticide Root Zone Model Ground Water (PRZM GW) model, the estimated drinking water concentrations (EDWCs) of boscalid for chronic exposures are estimated to be 26.4 ppb for surface water and 697 ppb for ground water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration of value 697 ppb was used to assess the contribution to drinking water.

3. From non-dietary exposure. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiteicides, and flea and tick control on pets). Boscalid is currently registered for the following uses that could result in residential exposures: Golf course turf, residential fruit and nut trees, and residential ornamentals and landscape gardens. EPA assessed residential exposure using the following assumptions:

All residential exposures are considered short-term in duration. The residential handler assessment included short-term exposures via the dermal and inhalation routes from treating residential ornamentals, landscape gardens, and trees.

In terms of post-application exposure, there is the potential for dermal post-application exposure for individuals as a result of being in an environment that has been previously treated with boscalid. Short-term dermal exposures were assessed for adults, youth 11 to 16 years old, and children 6 to 11 years old. Incidental oral exposure to children 1 to 2 years old is not expected from treated turf because boscalid is registered for use only on golf course turf and residential gardens and trees, and the extent to which young children utilize these areas is low.

The scenarios used in the aggregate assessment were those that resulted in the highest exposures. The highest exposures for all age groups were associated with only residential post-application dermal exposures, not inhalation exposures, and consist of the following:

- The residential dermal exposure for use in the adult aggregate assessment reflects dermal exposure from post-application activities on treated gardens.
- The residential dermal exposure for use in the youth (11–16 years old) aggregate assessment reflects dermal exposure from post-application golfing on treated turf.
- The residential dermal exposure for use in the child (6–11 years old) aggregate assessment reflects dermal exposure from post-application activities in treated gardens.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found boscalid to share a common mechanism of toxicity with any other substances, and boscalid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that boscalid does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.
D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure. EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. Prenatal and postnatal sensitivity. There was no evidence of increased susceptibility in the rat developmental study as no developmental toxicity was seen at the highest dose tested (limit dose). There was evidence of increased qualitative susceptibility in the rabbit developmental study as characterized by an increased incidence of abortions or early delivery at the limit dose. It could not be ascertained if the abortions were the result of a treatment-related effect on the dams, the fetuses or both. It was concluded that the degree of concern is low because the increased abortions or early delivery was seen only at the limit dose and the abortions may have been due to maternal stress.

There was evidence of increased quantitative susceptibility seen in the rat 2-generation reproduction study and the developmental neurotoxicity study, in that reduced body weights were seen in the offspring at dose levels where no parental toxicity was observed. However, the degree of concern is low because the dose selected for chronic dietary and non-dietary exposure risk assessments is lower than the dose that caused the body weight effects, and the effect was shown to be reversible in the developmental neurotoxicity study.

3. Conclusion. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x for all scenarios except for inhalation exposures where the 10X FQPA SF was retained. That decision is based on the following findings:

i. There is no indication that boscalid is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

ii. For the reasons listed in Unit III.D.2., the Agency has concluded that there are no residual uncertainties concerning the potential for prenatal and post-natal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to boscalid in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by boscalid.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. Acute risk. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, boscalid is not expected to pose an acute risk.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to boscalid from food and water will utilize 57% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of boscalid is not expected.

3. Short-term risk. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Boscalid is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to boscalid.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 300 for adults, 660 for youths 11 to 16 years old and 300 for children 6 to 11 years old. Because EPA’s level of concern for boscalid is a MOE of 100 or below, these MOEs are not of concern.

4. Intermediate-term risk. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for boscalid.

5. Aggregate cancer risk for U.S. population. Based on the data summarized in Unit III.A., EPA has concluded that the cPAD is protective of possible cancer effects. Given the results of the chronic risk assessment, cancer risk resulting from exposure to boscalid is not of concern.

6. Determination of safety. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to boscalid residues.

IV. Other Considerations

A. Analytical Considerations

Adequate enforcement methodology (gas chromatography/mass spectrometry (GC/MS)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305–2905;
email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for boscalid in or on several of the commodities that are different than the tolerances established for boscalid in the United States, however, the tolerance expression in the U.S. differs from the Codex MRL expression. Also, the submitted residue data support higher tolerance levels than those set by Codex, indicating that harmonization would cause legal application of pyraclostrobin by U.S. users to result in exceedances of domestic tolerances. Therefore, further harmonization of U.S. tolerances with Codex MRLs is not possible at this time.

C. Revisions to Petitioned-For Tolerances

The petitioner proposed a tolerance of 50 ppm for the Brassica, leafy greens, subgroup 4–16B, but the Agency is establishing the tolerance at 60 ppm, based on the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures. The Agency has also modified some of the tolerances to be consistent with EPA’s policy on significant figures.

V. Conclusion

Therefore, tolerances are established for residues of boscalid in or on Brassica, leafy greens subgroup 4–16B, except watercress at 60 ppm; celtuce at 45 ppm; Florence fennel at 45 ppm; kohlrabi at 6.0 ppm; leaf petiole vegetable subgroup 22B at 45 ppm; leafy greens subgroup 4–16A at 70 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 2.5 ppm; pea and bean, succulent shelled, subgroup 6B at 0.60 ppm; vegetable, Brassica, head and stem, group 5–16 at 6.0 ppm; vegetable, cucurbit, group 9 at 3.0 ppm; and vegetable, root, except sugar beet, subgroup 1B at 2.0 ppm.

Additionally, the following existing tolerances and inadvertent tolerances are removed as unnecessary due to the establishment of the new tolerances.

**Tolerances: Brassica**, head and stem, subgroup 5A: Brassica, leafy greens, subgroup 5B; cucumber, leaf petioles, subgroup 4B; leafy greens, subgroup 4A, except head lettuce and leaf lettuce; lettuce, head; lettuce, leaf; pea and bean, dried shelled, except soybean, subgroup 6C, except cowpea, field pea, and grain lupin; pea and bean, succulent shelled, subgroup 6B, except cowpea; turnip, greens; vegetable, cucurbit, group 9, except cucumber; vegetable, root, subgroup 1A, except sugar beet, garden beet, radish, and turnip. **Inadvertent tolerances:** beet, garden, roots; cowpea, seed; lupin, grain, grain; pea field, seed; radish, roots; turnip, roots.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDC section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it 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).

Since tolerances and exemptions that are established on the basis of a petition under FFDC section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDC section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not 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. 1501 et seq.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), EPA will submit a report containing this rule 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. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.


Michael Goodis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:
## Part 180—[Amended]

1. The authority citation for part 180 continues to read as follows:


2. In §180.589:
   a. In the table to paragraph (a);
   iii. Remove the entries “Cowpea, seed”; “Lupin, grain, grain”; “Pea field, seed”; “Radish, roots”; and “Turnip, roots”.
   b. Remove from the table in paragraph (d) the entries “Beet, garden, roots”;
   c. In the table to paragraph (a):
   i. Add in alphanumeric order entries
      a. In the table to paragraph (a):
      iv. Remove the entries “Cowpea, seed”; “Lupin, grain, grain”; “Pea field, seed”; “Radish, roots”; and “Turnip, roots”.

### Table: Commodity Tolerances for Residues

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Parts per million</th>
</tr>
</thead>
<tbody>
<tr>
<td>* * * * *</td>
<td>* * * * *</td>
</tr>
<tr>
<td>Brassica, leafy greens, subgroup 4–16B, except watercress</td>
<td>60</td>
</tr>
<tr>
<td>* * * * *</td>
<td>* * * * *</td>
</tr>
<tr>
<td>Celtuce</td>
<td>45</td>
</tr>
<tr>
<td>* * * * *</td>
<td>* * * * *</td>
</tr>
<tr>
<td>Fennel, Florence</td>
<td>45</td>
</tr>
<tr>
<td>* * * * *</td>
<td>* * * * *</td>
</tr>
<tr>
<td>Kohlrabi</td>
<td>6.0</td>
</tr>
<tr>
<td>Leaf petiole vegetable subgroup 22B</td>
<td>45</td>
</tr>
<tr>
<td>Leafy greens subgroup 4–16A</td>
<td>70</td>
</tr>
<tr>
<td>* * * * *</td>
<td>* * * * *</td>
</tr>
<tr>
<td>Pea and bean, dried shelled, except soybean, subgroup 6C</td>
<td>2.5</td>
</tr>
<tr>
<td>* * * * *</td>
<td>* * * * *</td>
</tr>
<tr>
<td>Pea and bean, succulent shelled, subgroup 6B</td>
<td>0.60</td>
</tr>
</tbody>
</table>

### BILLING CODE 6560–50–P

**Environmental Protection Agency**

**40 CFR Part 180**


**Tetrahydrofurfuryl Alcohol; Exemption From the Requirement of a Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation amends the requirement of a tolerance for residues of tetrahydrofurfuryl alcohol (THFA) (CAS Reg. No. 97–99–4) when used as an inert ingredient in pesticide formulations to add one herbicide application prior to the bloom growth stage and to establish a maximum permissible level for residues of tetrahydrofurfuryl alcohol.

**DATES:** This regulation is effective October 19, 2018. Objections and requests for hearings must be received on or before December 18, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0098, is available at http://www.regulations.gov or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Blvd., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. 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 OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

**FOR FURTHER INFORMATION CONTACT:** Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: RDFNNotices@epa.gov.

**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. **How can I get electronic access to other related information?**


C. **How can I file an objection or hearing request?**

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure…
proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2013–0098 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before December 18, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2013–0098, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions and submit comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- 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 docketing generally, is available at http://www.epa.gov/dockets.

II. Petition for Exemption

In the Federal Register of February 27, 2013 (78 FR 13295) (FRL–9380–2), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8080) by Toxcel, LLC, 7140 Heritage Village Plaza, Gainesville, VA 20156 on behalf of Penn A Kem, LLC, the petitioner, which referenced a summary of the petition prepared by Toxcel, LLC, on behalf of Penn A Kem, LLC, announcing the filing of a pesticide petition to supersede the previously submitted petition. EPA issued a document in the Federal Register of April 6, 2015 (80 FR 18327) (FRL–9924–001), pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of this revised petition. The revised petition requested that 40 CFR 180.1263 be amended to allow one herbicide application prior to the preboot stage for wheat, buckwheat, barley, oats, rye, sorghum, triticate, rice, and wild rice; extend the use on canola to the early bolting stage; extend the use on soybeans up to the bloom growth stage; and allow two herbicide applications to field corn and popcorn up to 36 inches tall (V8 stage). That document referenced a summary of the petition prepared by Toxcel, LLC, on behalf of Penn A Kem, LLC, the petitioner, which is available in the docket, http://www.regulations.gov. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. In making this safety finding, EPA is required to take into account the considerations set forth in section 408(b)(2)(C) and (D). 21 U.S.C. 346a(c)(2)(B). Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for tetrahydrofurfuryl alcohol including exposure resulting from the exemption established by this action. EPA’s assessment of exposures and risks associated with tetrahydrofurfuryl alcohol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of
the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by tetrahydrofurfuryl alcohol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://www.regulations.gov in the document “Hazard Assessment for the Tolerance Reassessment of Tetrahydrofurfuryl alcohol (THFA)(CAS Reg. No. 97–99–4)” at pp 8–12 in docket ID number EPA–HQ–OPP–2013–0098. A summary of the toxicity of tetrahydrofurfuryl alcohol as given in that document follows.

Acute toxicity information is available for the oral route with an LD50 for the rat of 1.6–3.2 g/kg. Tetrahydrofurfuryl alcohol was not irritating to the skin of mice but was irritating to the eyes of rabbits. Acute dermal and inhalation toxicity, as well as dermal sensitization information, are not available. However, there are reports that suggest tetrahydrofurfuryl alcohol may be moderately irritating via the dermal and inhalation routes of exposure to humans.

Although data on chronic effects is unavailable, subchronic studies indicate that systemic effects from repeated dermal and oral exposure to tetrahydrofurfuryl alcohol include increased body weight and body weight gain. Tetrahydrofurfuryl alcohol also exhibits adverse reproductive and developmental effects, and potential effects on the endocrine system.

Males are not only quantitatively more sensitive to the subchronic effects of tetrahydrofurfuryl alcohol than females, but the male reproductive system appears to be a target for tetrahydrofurfuryl alcohol. Consistent decreases in male reproductive organ weights (testicular, epididymal, and seminal vesicle) were observed in rats in the 90-day dietary (LOAEL 339 mg/kg/day), dermal (LOAEL 300 mg/kg/day), and inhalation (LOAEL <0.21 mg/L/day) toxicity studies. In addition, a 90-day oral (dietary) study in dogs revealed decreased testes weights of males in all treated groups (1,000, 3,000, 6,000 ppm, equivalent to approximately 25, 75, and 150 mg/kg/day), compared to controls, with severe testicular atrophy in all males at the highest dose (6,000 ppm or 150 mg/kg/day). Decreased spermatogenic activity was noted in males of the 3,000 ppm group (75 mg/kg/day) and was interpreted as a prodromal sign of atrophy.

A 28-day repeated oral (gavage) study in rats revealed significant decreases in absolute testes and epididymal weights after 28 days at a dose level of 600 mg/kg/day which continued through the 14-day recovery period. Necrosis of the seminiferous tubular epithelium of the testes was also observed in males of the 150 and 600 mg/kg/day group at 28 days. Necrosis of the testes was also observed in males of the 600 mg/kg/day group at the end of the 14-day recovery period.

In the reproduction/developmental toxicity screening test in rats, no reproductive parameters were affected except slightly increased gestation length at the high dose of 150 mg/kg/day.

The endocrine system may also be a target for tetrahydrofurfuryl alcohol. Alterations in pituitary, thymus, adrenal, and thyroid weights have been reported after subchronic exposure (28 days) to 600 mg/kg/day in male rats and pituitary weights at 150 mg/kg/day in female rats. Decreased absolute and relative adrenal weights were observed in males and females receiving 5,000 ppm (equivalent to 339 mg/kg/day males and 401 mg/kg/day females).

In one developmental toxicity study in rats a quantitative susceptibility based on decreased fetal body weights and a qualitative susceptibility based on increased incidence of filamentous tail was observed. However, in a more recent reproduction/developmental toxicity screening test (OECD 421 guideline study) in rats, an increased incidence of filamentous tail was not evident nor was there any other evidence of increased qualitative susceptibility. Based on the overall weight of evidence for developmental toxicity, it is determined that there is increased quantitative susceptibility but not increased qualitative susceptibility.

A neurotoxicity study is not available for tetrahydrofurfuryl alcohol, however no neurotoxic effects were observed in the available subchronic oral, dermal and inhalation toxicity studies.

Mutagenicity studies indicate tetrahydrofurfuryl alcohol is not mutagenic in Salmonella typhimurium or E. coli with or without metabolic activation. Tetrahydrofurfuryl alcohol was also negative for causing structural chromosomal aberrations or polyploidy with or without metabolic activation in cultured Chinese hamster lung cells.

There are currently no chronic toxicity or cancer studies available for tetrahydrofurfuryl alcohol. The Agency used a qualitative structure activity relationship (SAR) database, DEREK Nexus, to determine if there were structural alerts for potential carcinogenicity for tetrahydrofurfuryl alcohol. No structural alerts for carcinogenicity were identified for tetrahydrofurfuryl alcohol. In the absence of any structural alerts and lack of mutagenicity concerns, tetrahydrofurfuryl alcohol is not expected to be carcinogenic.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see http://www.epa.gov/pesticides/factsheets/riskassess.htm. A discussion of the toxicological endpoints for tetrahydrofurfuryl alcohol used for human risk assessment can be found at http://www.regulations.gov in the document “Hazard Assessment for the Tolerance Reassessment of Tetrahydrofurfuryl alcohol (THFA) (CAS Reg. No. 97–99–4) at pp 6–8 in docket ID number EPA–HQ–OPP–2013–0098”. A summary of the toxicological dose and endpoints for THFA follows:
### Table 1—Summary of Toxicological Doses and Endpoints for Tetrahydrofurfuryl Alcohol for Use in Human Risk Assessment

<table>
<thead>
<tr>
<th>Exposure/scenario</th>
<th>Point of departure and uncertainty/safety factors</th>
<th>RID, PAD, LOC for risk assessment</th>
<th>Study and toxicological effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dietary (Females 13–50 years of age).</td>
<td>NOAEL = [50] mg/kg/day. UF_A = [10]x UF_H = [10]x FOPA SF = [10]x</td>
<td>Acute RID = [0.5] mg/kg/day. aPAD = [0.05] mg/kg/day</td>
<td>[Developmental rat]. LOAEL = [100] mg/kg/day based on [decreased fetal body weight and increased incidence of filamentous tail, complete resorptions at 500 and 1,000 mg/kg/day].</td>
</tr>
<tr>
<td>Acute dietary (General population including infants and children).</td>
<td>None</td>
<td>NA</td>
<td>No acute effects relevant to the general population were observed in the available studies.</td>
</tr>
<tr>
<td>Chronic dietary (All populations)</td>
<td>NOAEL= [50] mg/kg/day. UF_A = [10]x UF_H = [10]x FOPA SF = [10]x</td>
<td>Chronic RID = [0.5] mg/kg/day. cPAD = [0.05] mg/kg/day</td>
<td>[Developmental rat]. LOAEL = [100] mg/kg/day based on [decreased fetal body weight and increased incidence of filamentous tail, complete resorptions at 500 and 1,000 mg/kg/day].</td>
</tr>
<tr>
<td>Incidental oral short-term (1 to 30 days).</td>
<td>NOAEL= [50] mg/kg/day. UF_A = [10]x UF_H = [10]x FOPA SF = [10]x</td>
<td>LOC for MOE = [1,000].</td>
<td>[Developmental rat]. LOAEL = [100] mg/kg/day based on [decreased fetal body weight and increased incidence of filamentous tail, complete resorptions at 500 and 1,000 mg/kg/day].</td>
</tr>
<tr>
<td>Dermal short-term (1 to 30 days).</td>
<td>Dermal study NOAEL = [100] mg/kg/day. UF_A = [10]x UF_H = [10]x FOPA SF = [10]x</td>
<td>LOC for MOE = [1,000].</td>
<td>[90-day dermal, rat]. LOAEL = [300 and 1,000] mg/kg/day M/F respectively based on [decreased sperm count and sperm production rate in males, lower body weight/gains in females].</td>
</tr>
<tr>
<td>Inhalation short-term (1 to 30 days).</td>
<td>Inhalation study LOAEL=0.21 mg/L. UF_A = [10]x UF_H = [10]x FOPA SF = [10]x</td>
<td>LOC for MOE = [1000].</td>
<td>[90-day inhalation, rat]. LOAEL = [0.21] mg/L (50 ppm; approx. 60 mg/kg/day) based on. Decreased body weight of males at 150 and 500 ppm. Multiple effects on sperm number, motility, and morphology at interim and terminal necropsy of males at both 150 and 500 ppm].</td>
</tr>
<tr>
<td>Cancer (Oral, dermal, inhalation).</td>
<td>Classification: No structural alerts for carcinogenicity were identified for tetrahydrofurfuryl alcohol using a qualitative structure activity relationship (SAR) database, DEREK Nexus. In the absence of any structural alerts and lack of mutagenicity concerns, tetrahydrofurfuryl alcohol is not expected to be carcinogenic.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RID = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of short-term study for long-term risk assessment. UF_S = use of a short-term study for long-term risk assessment.

### C. Exposure Assessment

1. **Dietary exposure from food and feed uses.** In evaluating dietary exposure to tetrahydrofurfuryl alcohol, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from tetrahydrofurfuryl alcohol in food as follows:

   - **Acute and chronic exposure.** In conducting the acute and chronic dietary exposure assessments using the Dietary Exposure Assessment Model (DEEM–FCID™, Version 3.18, EPA used food consumption information from the U.S. Department of Agriculture’s (USDA’s) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA).

   In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper-bound exposure estimates for the subject inert ingredient. Upper-bound exposure estimates are based on the highest tolerance for a given commodity from a list of high-use insecticides, herbicides and fungicides. A complete discussion of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled “Alkyl Amines Polyethoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessment for the Inerts” (D361707, S. Piper 2/25/09) and can be found at http://www.regulations.gov in docket ID number EPA–HQ–OPP–2008–0738.

   In the case of tetrahydrofurfuryl alcohol residues resulting from foliar applications, EPA made specific adjustments to the dietary exposure assessments to account for the use limitations of tetrahydrofurfuryl alcohol as well as some residue chemistry data (plant uptake data) submitted with the petition. The use of the dietary estimated exposure model (DEEM) for upper-bound dietary risk assessments as described above was modified to include only those commodities on which pesticide formulations containing tetrahydrofurfuryl alcohol are being
used or are proposed to be used. Specifically, the dietary exposure assessment considered foliar uses of tetrahydrofurfuryl alcohol on wheat, buckwheat, barley, oats, rye, sorghum, triticale, rice and wild rice, canola, cotton, field corn, and popcorn as contained in the existing tolerance exemption expression and that are the subject of the present petitions. A residue chemistry study (a radiolabeled plant uptake study with THFA in corn, tomato, and wheat) suggest that the highest reported detectable level of tetrahydrofurfuryl alcohol residues resulting from foliar application in these crops is 0.5 ppm and this value is used in the dietary exposure assessment for the commodities included in the tolerance exemption.

For seed treatment use, it was conservatively assumed that all of the following commodities (which represent an agglomeration of all commodities for which seed treatment pesticide products are approved for use) could potentially be treated with a seed treatment pesticide containing tetrahydrofurfuryl alcohol: barley, corn (field, pop, sweet and corn for seed production), legume vegetables (dried shelled peas and beans), brassica and bulb vegetables, alfalfa, cucurbits, rye, wheat, cotton, sugar beets, and sunflowers. For seed treatment use, in the absence of THFA-specific data, residue chemistry data for active ingredients with seed treatment uses were utilized. Residue levels for pesticide active ingredients used for seed treatment are all below the limit of detection, so a highly conservative value of 0.05 ppm is used in the dietary exposure assessment as a residue value for THFA for all seed treatment commodities based on application of Agency policies for assigning values to nondetected/nonquantified pesticide residues.

3. Dietary exposure from drinking water. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for tetrahydrofurfuryl alcohol a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

4. From non-dietary exposure. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Tetrahydrofurfuryl alcohol is contained in a pesticide currently registered for uses that could result in residential exposures. The use pattern of the product includes application to dogs. EPA assessed this residential exposure using the Agency’s Standard Operating Procedures for Residential Pesticide Exposure Assessment Residential Exposure (Residential SOP). Based on the Treated Pets section of the Residential SOP, the following assumptions are made: for residential handlers, exposure (dermal and inhalation) is expected to be short-term only. Residential post-application dermal exposure (short-term only) was assessed for adults and children. Residential post-application inhalation exposure is generally not assessed for pet treatment product uses as such exposure is typically considered to be negligible. Incidental oral post-application exposure was assessed for children 1 to 2 years old. All post-application exposures are expected to be short-term in duration. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at http://www.epa.gov/pesticides/trac/science/trac6a05.pdf.

5. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found tetrahydrofurfuryl alcohol to share a common mechanism of toxicity with any other substances, and tetrahydrofurfuryl alcohol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tetrahydrofurfuryl alcohol does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. Prenatal and postnatal sensitivity. The data available for evaluation suggest there is evidence of increased quantitative susceptibility of the offspring after in utero exposure to tetrahydrofurfuryl alcohol. No reproductive parameters were affected except slightly increased gestation length at the high dose of 150 mg/kg/day in the OECD 421 study in rats. There is also a concern for the effects of tetrahydrofurfuryl alcohol on the developing male reproductive system. Subchronic and reproductive toxicity studies consistently revealed decreased testicular epididymis and seminal vesicle weights as well as atrophy of the epididymis and seminal vesicles and abnormal morphology and motility of sperm. The level at which tetrahydrofurfuryl alcohol may affect the reproductive system during development is currently not known.

3. Conclusion. EPA has determined that based on evidence of qualitative and quantitative susceptibility the safety of infants and children would be adequately protected if the FQPA SF was retained at 10x for all scenarios. That decision is based on the following findings:

i. The toxicity database for tetrahydrofurfuryl alcohol consists of a 28-day and 90-day oral toxicity studies in rats, dogs, 90-day dermal toxicity study in rats, 90-day inhalation toxicity study in rats, several mutagenicity studies, developmental/reproductive toxicity screening study in rats, and a developmental toxicity study and reproductive toxicity study in rats.

ii. Slight atrophy of thymus was seen in high dose animal groups in the 28-day oral toxicity study, which may be indicative of an immune response, however no guideline immunotoxicity study is available.

iii. Evidence of increased quantitative susceptibility of offspring is seen in the developmental toxicity study.

iv. Additionally, alterations in the male reproductive system from subchronic exposure to tetrahydrofurfuryl alcohol does indicate
a concern for effects to the developing male reproductive system.

v. The FQPA factor of 10X is considered adequate to account for potential immunotoxicity and uncertainty regarding the developing reproductive system in males because clear NOAELs are established in the available database.

vi. There are no residual uncertainties identified in the exposure databases. As described earlier, EPA used highly conservative assumptions for the dietary food exposure assessment. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tetrahydrofurfuryl alcohol in drinking water. EPA used similarly conservative assumptions to assess residential exposures of children to tetrahydrofurfuryl alcohol. These assessments will not underestimate the exposure and risks.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. Acute risk. Using the exposure assumptions discussed in this unit for acute exposure, EPA has concluded that acute exposure to tetrahydrofurfuryl alcohol from food and water will utilize 8.88% of the aPAD for females 13–49 years old.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tetrahydrofurfuryl alcohol from food and water will utilize 8.5% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of tetrahydrofurfuryl alcohol is not expected.

3. Short-term risk. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Tetrahydrofurfuryl alcohol is contained in a pesticide currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to tetrahydrofurfuryl alcohol.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined chronic food, water, and short-term residential exposures result in aggregate MOEs of 13,100 for adults and 9,800 for children 1–2 years old. Because EPA’s level of concern for tetrahydrofurfuryl alcohol is a MOE of 1,000 or below, these MOEs are not of concern.

4. Intermediate-term risk. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, tetrahydrofurfuryl alcohol is not contained in any pesticide products registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for tetrahydrofurfuryl alcohol.

5. Cancer. Based on the lack of genotoxicity and a DEREK assessment of tetrahydrofurfuryl alcohol that revealed no structural alerts suggestive of carcinogenicity, tetrahydrofurfuryl alcohol is therefore not expected to pose a cancer risk to humans.

6. Determination of safety. Taking into consideration all available information on tetrahydrofurfuryl alcohol, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to tetrahydrofurfuryl alcohol resulting from the limited uses contained in 40 CFR 180.1263. Therefore, the amendment of the exemption from requirement of a tolerance at 40 CFR 180.1263 for residues of tetrahydrofurfuryl alcohol when used as an inert ingredient in pesticide formulations, which is a small amount of one herbicide application prior to the pre-boot stage to wheat, buckwheat, barley, oats, rye, sorghum, triticale, rice and wild rice; extended use on canola to the early bolting stage; extended use on soybeans up to the bloom stage; and allowance of two applications to field corn and popcorn up to 36 inches tall (V8 stage) is safe under FFDCA section 408.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VI. Conclusion

Therefore, the exemption from the requirement of a tolerance under 40 CFR 180.1263 is amended to add exemption from the requirement of a tolerance for residues of tetrahydrofurfuryl alcohol (CAS Reg. No. 97–99–4) when used as an inert ingredient (solvent) in herbicides applied to wheat, buckwheat, barley, oats, rye, sorghum, triticale, rice and wild rice prior to the pre-boot stage; use on canola to the early bolting stage; use on soybeans up to the bloom stage; and two applications to field corn and popcorn up to 36 inches tall (V8 stage).

VII. Statutory and Executive Order Reviews

This final rule establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it 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). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as...
the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 et seq.). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 et seq.), EPA will submit a report containing this rule 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. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 9, 2018.

Michael Goodis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:


2. In § 180.1263, revise paragraphs (d) and (e), and add paragraphs (f) and (g) to read as follows:

§ 180.1263 Tetrahydrofurfuryl alcohol; exemption from the requirement of a tolerance.

(d) For use in herbicides with one application to wheat, buckwheat, barley, oats, rye, sorghum, triticale, rice, and wild rice prior to the pre-boot stage.

(e) For use in herbicides with two applications to field corn and popcorn up to 36 inches tall (V8 stage).

(f) For use in herbicides with two applications to canola prior to the early bolting stage.

(g) For use in herbicides with two applications to soybeans prior to the bloom growth stage.

[FR Doc. 2018–22862 Filed 10–18–18; 8:45 am]
BILLING CODE 6560–50–P
DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 905 and 944

[Doc. AMS–SC–18–0046; SC18–905–3 PR]

Oranges, Grapefruit, Tangerines, and Pummelos Grown in Florida and Imported Grapefruit; Change in Grade and Size Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule invites comments on a recommendation from the Citrus Administrative Committee (Committee) to relax the minimum grade requirements for oranges and tangerines, remove grade and size requirements for Ambersweet and Temple oranges, and simplify the tables outlining the grade and size requirements for interstate and export shipments currently prescribed under the marketing order for oranges, grapefruit, tangerines, and pummelos grown in Florida. A corresponding change would be made to the grapefruit import regulation as required by section 8e of the Agricultural Marketing Agreement Act of 1937.

DATES: Comments must be received by November 19, 2018.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or internet: http://www.regulations.gov. All comments should reference the document number and the date and page number of this issue of the Federal Register and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: http://www.regulations.gov. All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Abigail Campos, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: Abigail.Campos@ams.usda.gov or Christian.Nissen@ams.usda.gov. Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: Richard.Lower@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, proposes amendments to regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposed rule is issued under Marketing Order No. 905, as amended (7 CFR part 905), regulating the handling of oranges, grapefruit, tangerines, and pummelos grown in Florida. Part 905 (referred to as the “Order”) is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the “Act.” The Committee locally administers the Order and is comprised of producers and handlers of citrus operating within the area of production, and a public member.

This rule is also issued under section 8e of the Act, which provides that whenever certain specified commodities, including grapefruit, are regulated under a Federal marketing order, imports of these commodities into the United States are prohibited unless they meet the same or comparable grade, size, quality, or maturity requirements as those in effect for the domestically produced commodities.

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this proposed rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB’s Memorandum titled “Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled ‘Reducing Regulation and Controlling Regulatory Costs’” (February 2, 2017).

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA’s ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of import regulations issued under section 8e of the Act.

This proposed rule invites comments on changes to the grade and size requirements under the Order. This proposal would relax the minimum grade requirements for oranges and Fall-glo, Sunburst, and Honey tangerines from U.S. No. 1 to U.S. No. 2. This action would also remove grade and size requirements for Ambersweet and Temple oranges and simplify the tables outlining the grade and size requirements for interstate and export shipments. These actions would maximize shipments by allowing more citrus to be shipped to the fresh market and would help increase returns to growers and handlers. These changes
were unanimously recommended by the Committee on April 26, 2018. Section 905.52 provides authority to establish minimum grade requirements for Florida citrus. Section 905.306 specifies, in part, the minimum grade requirements for citrus. Requirements for domestic shipments are specified in §905.306 in Table I of paragraph (a) and for export shipments in Table II of paragraph (b). Minimum grade and size requirements for grapefruit imported into the United States are currently in effect pursuant to §944.106.

The Committee met on April 26, 2018, and discussed ways to provide additional supplies of Florida citrus to the marketplace and increase grower and handler returns. Committee members recognized that with the ongoing impacts of citrus greening, some adjustments should be made to assist growers and handlers and provide for the utilization of additional volume of Florida citrus in the fresh market. Citrus caused the steady decline in Florida citrus production and has spread to all citrus producing counties in Florida. From the 2011–12 to the 2016–17 season, citrus greening has reduced Florida’s orange production by 53 percent and tangerine production by 67 percent. During the same period, fresh shipments have declined by 54 percent for oranges and 80 percent for tangerines.

The industry suffered additional production losses as a result of damage from Hurricane Irma in September 2017. According to USDA’s National Agricultural Statistics Service (NASS), production for the 2016–17 season totaled 68.8 million boxes for oranges and 1.6 million boxes for tangerines. For the 2017–18 season, the forecasted production is expected to decrease by 34 percent for oranges and 53 percent for tangerines. Also, the citrus trees may take several seasons to recover from the hurricane damage, further impacting production and supply.

Given the decrease in production, the Committee recommended relaxing the minimum grade requirements for oranges and Fallglo, Sunburst, and Honey tangerines from U.S. No. 1 to U.S. No. 2. During the discussion of this change, one Committee member stated the reduction in grade could help address the limited volumes of fruit available in the market. It was also stated that there was a good fresh juice market for the U.S. No. 2 orange and that this change could help promote the sale of more oranges for the fresh juice market.

For tangerines, it was stated that the very limited volume of tangerines being produced in Florida was causing a supply concern for shippers. Members agreed that lowering the grade for tangerines would promote increased shipments.

The Committee believes relaxing the grade from U.S. No. 1 to U.S. No. 2 for oranges and Fallglo, Sunburst, and Honey tangerines would allow growers and handlers to utilize a greater percentage of the crop and would make more fruit available for shipment. By implementing this change, the industry would be able to put an additional 300,000 cartons or more into the fresh market, helping to maximize shipments and to increase grower and handler returns.

The Committee also discussed the limited production of Ambersweet and Temple oranges (also known as Royal tangerines). In the past, the Committee has considered removing the grade and size requirements for varieties with limited commercial value due to the very limited supplies available for shipment. Last season, Ambersweet oranges accounted for 4,280 cartons and Temple oranges accounted for a total of 40,227 cartons sold. Given the decline in production, the Committee recommended removing restrictions on grade and size for Ambersweet and Temple oranges to maximize remaining shipments.

The Committee also recommended simplifying Table I and Table II in §905.306, which outline the grade and size requirements for interstate and export shipments, to have them better reflect current industry requirements. Over the past few years, the Committee has made ongoing changes to both grade and size for a number of Florida citrus varieties. These changes have moved grade and size requirements toward greater commonality for both oranges and grapefruit.

With the grade change considered above, there would be no differences in grade and size requirements for the various types and varieties of oranges listed in the table. Therefore, the Committee recommended that “Early and midseason” oranges be consolidated with “Navel” and “Valencia and other late type” oranges into one “Oranges” classification. For grapefruit, the grade and size requirements for the two listed categories are already the same. “Seedless, red” and “Seedless, except red” would be combined into one “Grapefruit, seedless” classification.

In addition, the Committee recommended removing the “Regulation Period” column from the two tables. With the exception of the dates listed in Table I for Valencia and other late type oranges, the various dates listed are no longer applicable and are not reflective of the current industry. The grade change proposed for oranges would also negate the need for the current dates listed for Valencia and other late type oranges. The Committee made these recommendations to simplify the tables to reflect changes in the industry.

Section 8e of the Act provides that when certain domestically produced commodities, including grapefruit, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. Because this proposed rule would combine “Seedless, red” and “Seedless, except red” into one classification for grapefruit in the two domestic handling regulation tables as well as remove the “Regulation Period” column from those tables, a corresponding change to the table in the grapefruit import regulations would be required.

Further, two minor administrative changes would be made to §944.106. In §944.106(c), the reference to “§905.306” would be revised to read “§905.306(a) through (d)” so that the requirements specifically applicable to imports are more clearly defined. Additionally, §944.106(d) would be updated to reflect the revised name of the Agricultural Marketing Service (AMS) program area that oversees federal marketing orders.

The Committee also recommended establishing new reporting requirements under the Order. That change is being considered under a separate rulemaking action.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 20 handlers of Florida citrus who are subject to regulation under the Order and approximately 500 citrus producers in the regulated area. There are approximately 500,000 citrus importers. Small agricultural service firms are defined by the Small Business
Administration (SBA) as those having annual receipts of less than $7,500,000, and small agricultural producers are defined as those having annual receipts of less than $750,000 (13 CFR 121.201).

According to data from NASS, the industry, and the Committee, the weighted average f.o.b. price for Florida citrus for the 2016–17 season was approximately $15.20 per carton with total shipments of 12.6 million cartons. Using the number of handlers, and assuming a normal distribution, the majority of handlers have average annual receipts of more than $7,500,000 ($15.20 times 12.6 million equals $191,520,000 divided by 20 handlers equals $9,576,000 per handler).

In addition, based on the NASS data, the weighted average grower price for the 2016–17 season was around $8.30 per carton of citrus. Based on grower price, shipment data, and the total number of Florida citrus growers, and assuming a normal distribution, the average annual grower revenue is below $750,000 (12.6 million cartons equals $104,580,000 divided by 500 growers equals $209,160 per grower).

South Africa, Peru, and Mexico are the major grapefruit-producing countries exporting grapefruit to the United States. In 2016, shipments of grapefruit imported into the United States totaled approximately 24,000 metric tons. Information from USDA’s Foreign Agricultural Service indicates that the dollar value of imported fresh grapefruit was approximately $11.2 million in 2016. Using this value and the number of importers (approximately 50), most importers would have annual receipts of less than $7,500,000 for grapefruit.

Based on the previously described estimates, the majority of handlers of Florida citrus may be classified as large entities, while the majority of growers and importers may be classified as small entities.

This proposed rule would relax the minimum grade requirements for oranges and tangerines from U.S. No. 1 to U.S. No. 2, remove grade and size requirements for Ambersweet and Temple oranges, and simplify the tables outlining the grade and size requirements for interstate and export shipments. These changes would help maximize shipments by allowing more citrus to be shipped to the fresh market and would provide some additional fruit to address the losses resulting from citrus greening and the September 2017 hurricane. This proposed rule would revise §905.306. Authority for this change is provided in §905.52. This proposed rule would also change §944.106 in the grapefruit import regulation and is required by section 8e of the Act.

This action is not expected to increase the costs associated with the Order’s requirements or the grapefruit import regulation. Rather, it is anticipated that this action would have a beneficial impact. Reducing the grade requirements would make additional fruit available for shipment to the fresh market, provide an outlet for fruit that may otherwise go unharvested, and afford more opportunity to meet consumer demand. These changes would provide additional fruit to fill the shortfalls caused by citrus greening and by Hurricane Irma. By maximizing shipments, this action would help provide additional returns to growers and handlers. Further, removing the grade and size requirements for Ambersweet and Temple oranges would also help maximize shipments of these varieties impacted by declining production.

The benefits of this rule would also be equally available to all growers, handlers, and importers, regardless of their size.

An alternative to this action would be to maintain the current minimum grade requirements for domestic shipments of oranges and tangerines. However, leaving the requirements unchanged would not make additional fruit available for shipment. Following the significant damage experienced by the industry from citrus greening and the September 2017 hurricane, maximizing shipments would help provide additional returns to growers and handlers. Therefore, this alternative was rejected.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Order’s information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0189, Fruit Crops. No changes in those requirements are necessary as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule will not impose any additional reporting or recordkeeping requirements on either small or large Florida citrus handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

The Committee’s meeting was widely publicized throughout the citrus industry, and all interested persons were invited to attend the meeting and participate in Committee deliberations. Like all Committee meetings, the April 26, 2018, meeting was a public meeting, and all entities, both large and small, were able to express their views on this issue. Interested persons are invited to submit comments on this proposed rule, including the regulatory and information collection impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: http://www.ams.usda.gov/rules-regulations/moa/small-businesses. Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the FOR FURTHER INFORMATION CONTACT section.

In accordance with section 8e of the Act, the United States Trade Representative has concurred with the issuance of this proposed rule.

A 30-day comment period is provided to allow interested persons to respond to this proposal. All written comments timely received will be considered before a final determination is made on this matter.

List of Subjects
7 CFR Part 905
Grapefruit, Marketing agreements, Oranges, Pummelos, Reporting and recordkeeping requirements, Tangelos, Tangerines.

7 CFR Part 944
Avocados, Food grades and standards, Grapefruit, Grapes, Imports, Kiwifruit, Limes, Olives, Oranges.

For the reasons set forth in the preamble, parts 905 and 944 are proposed to be amended as follows:

PART 905—ORANGES, GRAPEFRUIT, TANGERINES, AND PUMMELOS GROWN IN FLORIDA

1. The authority citation for part 905 and part 944 continues to read as follows:


2. Amend §905.306 by...
§ 905.306 Orange, Grapefruit, Tangerine and Tangelo Regulation.

(a) No handler shall ship between the production area and any point outside thereof, in the 48 contiguous States and the District of Columbia of the United States, any variety of fruit listed in column (1) of Table I to paragraph (a), except for Ambersweet and Temple, unless such variety meets the applicable minimum grade and size (with tolerances for size as specified in paragraph (c) of this section) specified for such variety in columns (2) and (3) of Table I to paragraph (a): Provided, That all grapefruit meet the minimum maturity requirements specified in paragraph (e) of this section.

(b) No handler shall ship to any destination outside the 48 contiguous States and the District of Columbia of the United States any variety of fruit listed in column (1) of Table II to paragraph (b), except for Ambersweet and Temple, unless such variety meets the applicable minimum grade and size (with tolerances for size as specified in paragraph (c) of this section) specified for such variety in columns (2) and (3) of Table II to paragraph (b): Provided, That all grapefruit meet the minimum maturity requirements specified in paragraph (e) of this section.

### TABLE I TO PARAGRAPH (a)

<table>
<thead>
<tr>
<th>Variety</th>
<th>Minimum grade</th>
<th>Minimum diameter (inches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oranges</td>
<td>U.S. No. 2</td>
<td>2–4/16</td>
</tr>
<tr>
<td>Grapefruit, Seedless</td>
<td>U.S. No. 1</td>
<td>3</td>
</tr>
<tr>
<td>Tangerines:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fallglo</td>
<td>U.S. No. 2</td>
<td>2–6/16</td>
</tr>
<tr>
<td>Honey</td>
<td>U.S. No. 2</td>
<td>2–6/16</td>
</tr>
<tr>
<td>Sunburst</td>
<td>U.S. No. 2</td>
<td>2–6/16</td>
</tr>
<tr>
<td>Tangelos</td>
<td>U.S. No. 1</td>
<td>2–8/16</td>
</tr>
</tbody>
</table>

### TABLE II TO PARAGRAPH (b)

<table>
<thead>
<tr>
<th>Variety</th>
<th>Minimum grade</th>
<th>Minimum diameter (inches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oranges</td>
<td>U.S. No. 2</td>
<td>2–4/16</td>
</tr>
<tr>
<td>Grapefruit, Seedless</td>
<td>U.S. No. 1</td>
<td>3</td>
</tr>
<tr>
<td>Tangerines:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fallglo</td>
<td>U.S. No. 2</td>
<td>2–6/16</td>
</tr>
<tr>
<td>Honey</td>
<td>U.S. No. 2</td>
<td>2–6/16</td>
</tr>
<tr>
<td>Sunburst</td>
<td>U.S. No. 2</td>
<td>2–6/16</td>
</tr>
<tr>
<td>Tangelos</td>
<td>U.S. No. 1</td>
<td>2–8/16</td>
</tr>
</tbody>
</table>

* * * * *

PART 944—FRUITS; IMPORT REGULATIONS

3. In § 944.106

§ 944.106 Grapefruit import regulation.

(a) * * *

### TABLE 1 TO § 944.106

<table>
<thead>
<tr>
<th>Grapefruit classification</th>
<th>Minimum grade</th>
<th>Minimum diameter (inches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grapefruit, seedless</td>
<td>U.S. No. 1</td>
<td>3</td>
</tr>
</tbody>
</table>

* * * * *

(c) Terms and tolerances pertaining to grade and size requirements, which are defined in the United States Standards for Grades of Florida Grapefruit (7 CFR 51.750–51.784), and in Marketing Order No. 905 (7 CFR 905.18 and 905.306(a) through (d)), shall be applicable herein.

(d) The Federal or Federal-State Inspection Service, Specialty Crops Program, Agricultural Marketing Service, United States Department of Agriculture, is designated as the governmental inspection service for certifying the grade, size, quality, and
maturity of grapefruit imported into the United States.

Bruce Summers,
Administrator, Agricultural Marketing Service.

[FR Doc. 2018–22758 Filed 10–18–18; 8:45 am]
BILLING CODE 3410–02–P

SEcurities and EXchange COMMISSION

17 CFR Part 240

[Release No. 34–84409; File No. S7–08–12]

RIN 3235–A112

Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital Requirements for Broker-Dealers

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule; reopening of comment period; request for additional comment.

SUMMARY: The Securities and Exchange Commission ("Commission") is reopening the comment period and requesting additional comment (including potential modifications to proposed rule language) on the following: Proposed amendments and new rules that would establish capital and margin requirements for security-based swap dealers ("SBSDs") and major security-based swap participants ("MSBSPs") that do not have a prudential regulator, establish segregation requirements for SBSDs, establish notification requirements for SBSDs and MSBSPs relating to segregation, and raise minimum net capital requirements and establish liquidity requirements for broker-dealers permitted to use internal models when computing net capital ("ANC broker-dealers"). The Commission also is reopening the comment period and requesting additional comment on proposed amendments that would establish the cross-border treatment of security-based swap capital, margin, and segregation requirements; and a proposed amendment that would establish an additional capital requirement for SBSDs that do not have a prudential regulator.

DATES: The comment periods for portions of the proposed rules published Nov. 23, 2012 (77 FR 70213); May 23, 2013 (78 FR 30967); and May 2, 2014 (79 FR 25193), are reopened.

Comments should be submitted by November 19, 2018.

ADdRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (http://www.sec.gov/rules/other.shtml) or
- Send an email to rule-comments@sec.gov. Please include File No. S7–08–12 on the subject line.

Paper Comments

- Send paper comments to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number S7–08–12. 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 of submission. The Commission will post all comments on the Commission’s website (http://www.sec.gov). Comments are also available for website 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. All comments received will be posted without change. Persons submitting comments are cautioned that we do not read or edit personal identifying information from comment submissions. You should submit only information that you wish to make publicly available.

Studies, memoranda, or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any such materials will be made available on the Commission’s website. To ensure direct electronic receipt of such notifications, sign up through the “Stay Connected” option at www.sec.gov to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: Michael A. Macchiariolo, Associate Director, at (202) 551–5525; Thomas K. McGowan, Associate Director, at (202) 551–5521; Randall W. Roy, Deputy Associate Director, at (202) 551–5522; Sheila Dombal Swartz, Senior Special Counsel, at (202) 551–5545; Timothy C. Fox, Branch Chief, at (202) 551–5687; Valentina Minak Deng, Special Counsel, at (202) 551–5778; or Nina Kostyukovsky, Attorney Advisor, at (202) 551–8833, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–7010.

SUPPLEMENTARY INFORMATION:

I. Background

In October 2012, the Commission proposed amendments and new rules to: (1) Establish capital and margin requirements for SBSDs and MSBSPs that do not have a prudential regulator ("nonbank SBSDs" and "nonbank MSBSPs"); (2) establish segregation requirements for SBSDs; (3) establish notification requirements for SBSDs and MSBSPs relating to segregation; and (4) raise minimum net capital requirements and liquidity requirements for ANC broker-dealers. The Commission published the 2012 Proposals largely pursuant to Title VII of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Title VII of the Dodd-Frank Act"). The Commission extended the comment period once, and reopened it once. The Commission has received a number of comment letters in response to the 2012 Proposals.

In addition, in May 2013, the Commission proposed provisions to establish the cross-border treatment of security-based swap capital, margin, and segregation requirements.

1 The term “prudential regulator” is defined in Section 1(a)(39) of the Commodity Exchange Act (7 U.S.C. 1(a)(39)) and that definition is incorporated by reference in Section 3(a)(74) of the Securities Exchange Act of 1934 ("Exchange Act" or "Act"). 15 U.S.C. 78c(a)(74). Pursuant to the definition, the Board of Governors of the Federal Reserve System ("FRB"), the Office of the Comptroller of the Currency ("OCC"), the Federal Deposit Insurance Corporation ("FDIC"), the Farm Credit Administration ("FCA"), or the Federal Housing Finance Agency ("FHFA") (collectively, the "prudential regulators") is the "prudential regulator" of an SBSD, MSBSP, swap participant, or major swap participant if the entity is directly supervised by that agency.


5 The comment letters are available at http://www.sec.gov/comments/s7-08-12/s70812.shtml.

6 Cross-Border Security-Based Swap Activities: Re-Proposal of Regulation SBSCR and Certain Rules and Forms Related to the Registration of Security-Based Swap Dealers and

Continued
Commission has received a number of comment letters in response to the 2013 Proposals.7 Finally, in April 2014, the Commission proposed an additional nonbank SBSD capital requirement.8 The Commission has received one comment letter in response to the 2014 Proposals.9

In the releases publishing the Proposals, the Commission described the statutory and regulatory background for the proposed amendments and rules, the rationales of the proposed amendments and rules, the potential economic consequences, including the baseline against which the proposed amendments and rules may be evaluated, the potential costs and benefits, reasonable alternatives, and the potential effects on efficiency, competition, and capital formation.10 Since publication of the 2012 Proposals, the Commission has adopted other rules relating to the regulation of the over-the-counter derivatives markets pursuant to Title VII of the Dodd-Frank Act.11 In addition, the prudential regulators and the Commodity Futures Trading Commission ("CFTC") have adopted or proposed rules under Title VII of the Dodd-Frank Act that are relevant to the Proposals.12

The Commission has carefully considered the comment letters, and the Commission believes it is prudent to reopen the comment period for the Proposals in light of these comments and regulatory developments. In addition, the Commission believes the public should have the opportunity to provide comment on the potential economic effects of the Proposals in light of regulatory and market developments since they were published. Accordingly, the Commission is reopening the public comment period for 30 days and seeking comment on all aspects of the Proposals. The Commission also is seeking specific comment on certain aspects of the Proposals where further information would be particularly helpful to the Commission. In particular, the Commission is seeking comment on potential rule language that would modify rule text that was in the Proposals. This modified rule language would be included in: (1) Existing rules 17 CFR 240.15c-3 ("Rule 15c3-1"), 17 CFR 240.15c-3-1a ("Appendix A to Rule 15c3-1"), 17 CFR 240.15c-3-3 ("Rule 15c3-3"), and 17 CFR 240.3a71-6 ("Rule 3a71-6"); (2) new rule 17 CFR 240.15c-3-3-3 ("Exhibit B to Rule 15c3-3"); and (3) in proposed rules 17 CFR 240.18a-1 ("Rule 18a-1"), 17 CFR 240.18a-1a ("Appendix A to Rule 18a-1"), 17 CFR 240.18a-3 ("Rule 18a-3"), 17 CFR 240.18a-4 ("Rule 18a-4"), and 17 CFR 240.18a-4a ("Exhibit A to Rule 18a-4"). Comment letters received by the Commission previously need not be re-submitted as they will continue to be a part of the public comment file for this rulemaking and considered by the Commission.

II. Request for Comment

The Commission renews its request for comment on all aspects of the Proposals and on the specific topics identified below. Commenters are requested to provide empirical data in support of any arguments and analyses. The Commission notes that comments are of the greatest assistance to rulemaking initiatives when accompanied by supporting data and analysis, and, if appropriate, accompanied by alternative approaches and suggested language.

Capital

1. The 2012 Proposals included a provision that would establish a financial ratio-derived minimum net capital requirement for a nonbank SBSD equal to eight percent (8%) of the firm’s risk margin amount.13 The risk margin amount would be the sum of:
• The greater of the total margin required to be delivered by the nonbank SBSD with respect to security-based swap transactions cleared for security-based swap customers at a clearing agency or the amount of the deductions (haircuts) that would apply to the cleared security-based swap positions of the security-based swap customers pursuant to the proposed capital requirements; and
• The total margin amount calculated by the nonbank SBSD with respect to non-cleared security-based swaps pursuant to the proposed margin rule.14

The total of these two amounts would be multiplied by eight percent (8%) to determine the dollar amount of this ratio requirement (and the nonbank SBSD’s minimum net capital requirement would be the greater of a

\[ \text{Risk Margin Amount} = \max(\text{MRNC}, \text{IMNC} \times 8) \]

where MRNC is the ratio-based minimum net capital requirement, IMNC is the amount of initial margin for cleared security-based swaps, and IMNC is the amount of haircuts applicable to the same cleared security-based swaps. As proposed, a stand-alone nonbank SBSD would be subject to this ratio-based minimum net capital requirement, whereas a nonbank SBSD dually registered as a broker-dealer would be subject to the sum of this ratio-based minimum net capital requirement plus one of the two existing financial ratio-based minimum net capital requirements in 15c3-1.
fixed-dollar amount and a ratio amount). The proposal for a ratio amount relating to security-based swaps was designed to establish a minimum net capital requirement that increases in tandem with an increase in the risks associated with a nonbank SBSD’s security-based swap activities. This scaled ratio amount is separate from the fixed-dollar amount that sets a floor to the minimum net capital requirement.15

a. The Commission requests comment and supporting data on the potential minimum net capital amounts that would be required of nonbank SBSDs as a result of the requirement, as proposed. How would those potential minimum net capital amounts compare with the amounts of capital currently maintained by entities that may register as nonbank SBSDs?

b. One commenter suggested that the Commission modify its proposed definition of the risk margin amount to reflect the lower risk associated with central clearing.16 In light of the comment and the goals of this provision, the Commission requests comment on whether the input to the risk margin amount for cleared security-based swap positions?17 The purpose of this potential modification would be to simplify the calculation, align it with the clearing agency margin requirements, and more closely align it with the CFTC’s existing rules and proposals.18

Would rule language as described below effect this potential modification to the rule text in the 2012 Proposals? If not, please explain why and suggest alternative rule language. If the Commission were to use the language described below, would it strike an appropriate balance in terms of achieving the objectives of the proposed rule and addressing the commenter’s concern described above? If not, please explain why and suggest alternative rule language that could more effectively and efficiently strike the balance and achieve the objective.

The potential modifications to paragraph (c)(17) of Rule 15c3–1 would provide that the term risk margin amount means the sum of: (i) The total initial margin required to be maintained by the broker or dealer at each clearing agency with respect to uncleared futures, foreign futures, and cleared swaps positions carried in customer and noncustomer accounts; and (ii) the total margin amount calculated by the broker or dealer with respect to non-cleared security-based swap transactions cleared for security-based swap customers; and (iii) the total margin amount calculated by the security-based swap dealer at each clearing agency with respect to security-based swap customers; and (iv) the total margin amount calculated by the security-based swap dealer with respect to non-cleared security-based swap transactions cleared for security-based swap customers pursuant to §240.18a–3(c)(1)(i)(B).

Similarly, the potential modifications to paragraph (c)(6) of Rule 18a–1 would provide that the term risk margin amount means the sum of: (i) The total initial margin required to be maintained by the security-based swap dealer at each clearing agency with respect to security-based swap transactions cleared for security-based swap customers; and (ii) the total margin amount calculated by the security-based swap dealer with respect to non-cleared security-based swap transactions cleared for security-based swap customers pursuant to §240.18a–3(c)(1)(i)(B). The purpose of these potential modifications is to establish a minimum capital amount that is less than the deduction that would apply to the security-based swap that is used to clear excess of eight percent (8%) of the risk margin on uncleared swaps.

2. The 2012 Proposals included a capital charge that would apply if a nonbank SBSD collects an amount of margin from a counterparty to a cleared security-based swap that is less than the deduction that would apply to the security-based swap if it was a proprietary position of the firm. This proposed requirement was designed to account for the risk of the counterparty defaulting by requiring the nonbank SBSD to maintain capital in the place of margin in an amount that is no less than would be required for a proprietary position. It was also designed to ensure that there is a standard minimum coverage for exposure to cleared security-based swap counterparties apart from the individual clearing agency margin requirements, which could vary among clearing agencies and over time.21

One commenter opposed this proposal stating that the requirement would “harm customers because it would provide an incentive for the collection of margin by nonbank SBSDs beyond the amount determined by the clearing agency.”22 In light of the comment and the goals of this provision, the Commission requests comment on whether this proposed capital charge should be modified to include a risk-based threshold under which the proposed capital charge need not be taken. Should the rule provide that the deduction need not be taken if the difference between the clearing agency margin amount and the haircut is less than one percent (1%) or some other percent of the nonbank SBSD’s tentative net capital23 and less than ten percent (10%) or some other percent of the counterparty’s net worth,24 and the aggregate difference across all counterparties is less than twenty-five percent (25%) or some other percent of the nonbank SBSD’s tentative net capital?25 The purpose of these thresholds would be to limit the nonbank SBSD’s exposure to a single counterparty as well as to establish a concentration limit across all counterparties. In addition, these thresholds would be scalable and have a more direct relation to the risk to the nonbank SBSD arising from its security-based swap activities.

Would rule language as described below effect this potential modification?26

17 17 CFR 240.15c3–3a, Note E(5) (using a ten percent (10%) of net capital threshold for the calculation of undue concentration charges).

18 See id. at 70223–24.

19 See Letter from Stuart J. Kaswell, Executive Vice President, Managed Funds Association (Feb. 22, 2013).

20 See id. at 70225–46.

21 See id.


23 See, e.g., Order Granting Conditional Exemption Under the Securities Exchange Act of 1934 in Connection with Portfolio Margining of Swaps and Security-Based Swaps, Exchange Act Release No. 68433 (Dec. 14, 2012), 77 FR 75211 (Dec. 19, 2012). Pursuant to this order, Commission staff granted conditional temporary approval to certain broker-dealers that are also registered as FCMs to participate in a credit default swap (CDS) portfolio margining program, subject to specified conditions. One condition requires a firm to calculate its net credit exposure to a client and if the client’s net credit exposure is in excess of one percent (1%) of the firm’s tentative net capital, the firm is required to either collect the net credit exposure above the one percent (1%) threshold in the form of margin from its client or take a capital charge equal to that amount. See, e.g., Letter to Keith Bailey, Barclays Capital Inc. from Michael A. Macchiarella, Division of Trading and Markets, Commission (June 7, 2013).

24 See, e.g., 17 CFR 240.15c3–3a, Note E(5) (using a twenty-five percent (25%) of tentative net capital threshold for when a broker-dealer must reduce debits in the customer reserve fund).
to the rule text in the 2012 Proposals? If not, please explain why and suggest alternative rule language. If the Commission were to use the language described below, would it strike an appropriate balance in terms of achieving the objectives of the proposed rule and addressing the commenter’s concern described above? If not, please explain why and suggest alternative rule language that could more effectively and efficiently strike the balance and achieve the objective.

The potential modifications to paragraph (c)(2)(iv)(A) of Rule 15c3–1 would provide the following deduction from net worth in lieu of collecting collateral for cleared security-based swaps and swap transactions: (i) Deducting the amount of the margin difference for each account carried by the broker or dealer for another person that holds cleared security-based swap or swap transactions. The margin difference is the amount of the deductions to the positions in the account calculated pursuant to paragraph (c)(2)(iv)(A) of this section, § 240.15c3–1b, or § 240.15c3–1e (as applicable), less the margin value of collateral held in the account. (2) Exception. The deduction required pursuant to paragraph (c)(2)(iv)(A) of this section need not be taken to the extent that: (i) The amount of the margin difference for the account does not exceed the lesser of 1 percent (1%) of the tentative net capital of the security-based swap dealer or ten percent (10%) of the net worth of the counterparty; and (ii) The amount of the margin difference for all accounts that hold security-based swaps or swaps does not exceed twenty-five percent (25%) of the tentative net capital of the security-based swap dealer.

3. The 2012 Proposals included a provision that a nonbank SBSD would be required to take a 100 percent (100%) capital charge when it does not collect variation or initial margin for noncleared security-based swaps because of an exception from collecting margin. The proposed capital charge was intended to require a nonbank SBSD to set aside net capital to address the risks that would otherwise be mitigated through the collection of variation and initial margin. As an alternative to taking the 100 percent (100%) charge, the Commission proposed that firms using internal models to calculate net capital could take a credit risk charge if the uncollected margin involved a transaction with a commercial end user. Commenters requested that nonbank SBSDs be permitted to apply the credit risk charge to other types of counterparties. In light of the comments and the goals of this provision, the Commission requests comment on whether the use of the credit risk charge should be expanded to other types of counterparties and transactions and whether the Commission should permit a firm to apply the credit risk charge for uncollected initial margin for security-based swaps and swap transactions with any type of counterparty and for uncollected variation margin for transactions with a commercial end user only? The purpose of limiting the application of the credit risk charge with respect to uncollected variation margin to transactions with commercial end users would be to reduce the types of unsecured receivables that qualify as allowable assets for net capital purposes and, thereby, promote the liquidity of the nonbank SBSD.

b. The Commission requests comment on whether the rule should establish a threshold for uncollected margin above which the use of the credit risk charge would not be permitted. Should there be a threshold when the aggregate amount of uncollected margin across all counterparties exceeds a level of the nonbank SBSD’s tentative net capital? Should the threshold apply to the aggregate amount of uncollected initial and variation margin or just to the aggregate amount of uncollected variation margin? The latter approach would focus the threshold on unsecured receivables that result from not collecting variation margin and, thereby, promote the liquidity of the nonbank SBSD. Should there be a threshold with respect to uncollected variation margin for security-based swap and swap transactions with commercial end users and should that threshold be ten percent (10%) or some other percent of the nonbank SBSD’s tentative net capital?

This threshold would be designed to limit the nonbank SBSD’s aggregate exposure arising from not collecting variation margin from commercial end users and would be scalable to the nonbank SBSD’s financial condition.

c. The potential modifications to the rule text in the 2012 Proposals discussed above in 3.a and 3.b would include: (1) Changing the proposed rule to permit a nonbank SBSD to apply the credit risk charge for uncollected initial margin for security-based swaps and swaps from any type of counterparty and for uncollected variation margin from a commercial end user; and (2) establishing a risk-based threshold with respect to uncollected variation margin from commercial end users. Would rule language as described below affect this potential modification to the rule text in the 2012 Proposals? If not, please explain why and suggest alternative rule language. If the Commission were to use the language described below, would it strike an appropriate balance in terms of achieving the objectives of the proposed rule and addressing commenters’ requests to apply the credit risk charge more broadly? If not, please explain why and suggest alternative rule language that could more effectively and efficiently strike the balance and achieve the objective.

The potential modifications to paragraph (a)(7) of Rule 15c3–1 would provide: In accordance with Appendix E to this section (§ 240.15c3–1e), the Commission may approve, in whole or in part, an application or an amendment to an application by a broker or dealer to calculate net capital using the market risk standards of appendix E to compute a deduction for market risk on some or

29 See id.
30 See id.
31 See id. at 70240–45.
32 See, e.g., Letter from Anne-Marie Leroy, Senior Vice President and Group General Counsel, and David Harris, Acting Vice President and General Counsel, The World Bank (Feb. 31, 2013).
33 See, e.g., 17 CFR 240.15c3–1(c)(2)(iv)(M)(1) (using a ten percent (10%) of tentative net capital threshold for the calculation of undue concentration charges).
all of its positions, instead of the provisions of paragraphs (c)(2)(vi) and (c)(2)(vii) of this section, and § 240.15c–3(b), and using the credit risk standards of Appendix E to compute a deduction for credit risk for certain security-based swap transactions, as specified in this paragraph, instead of the provisions of paragraphs (c)(2)(iv), (c)(2)(v), (c)(1)(x), and (c)(2)(v) of this section, subject to any conditions or limitations on the broker or dealer the Commission may require as necessary or appropriate in the public interest or for the protection of investors. A broker or dealer may use the credit risk standards of Appendix E to compute a deduction for credit risk for security-based swap transactions with commercial end users as long as that term is defined in § 240.18a–3(b)(2), and swap transactions in which a counterparty qualifies for an exception from margin requirements pursuant to Section 4s(e)(4) of the Commodity Exchange Act (7 U.S.C. 6s(e)(4)) instead of the provisions of paragraph (c)(1)(x)(B)(1) of this section, and, for swap transactions instead of the provisions of paragraph (c)(1)(x)(B)(2) of this section.

Similarly, the potential modifications to paragraph (a)(2) of Rule 18a–1 would provide: In accordance with paragraph (d) of this section, the Commission may approve, in whole or in part, an application or an amendment to an application by a security-based swap dealer to calculate net capital using the market risk standards of paragraph (d) to compute a deduction for market risk on some or all of its positions, instead of the provisions of paragraphs (c)(1)(iv), (vi), and (vii) of this section, and § 240.18a–1b, and using the credit risk standards of paragraph (d) to compute a deduction for certain security-based swap and swap transactions, as specified in this paragraph, instead of the provisions of paragraphs (c)(1)(iii), (c)(1)(ix)(B)(1), and (c)(1)(ix)(B)(2) of this section, subject to any conditions or limitations on the security-based swap dealer the Commission may require as necessary or appropriate in the public interest or for the protection of investors. A security-based swap dealer may use the credit risk standards of paragraph (d) to compute a deduction for credit risk for security-based swap transactions with commercial end users as that term is defined in § 240.18a–3(b)(2), and swap transactions in which a counterparty qualifies for an exception from margin requirements pursuant to Section 4s(e)(4) of the Commodity Exchange Act (7 U.S.C. 6s(e)(4)) instead of the provisions of paragraph (c)(1)(iii) of this section, provided that the deductions, in the aggregate, do not exceed ten percent (10%) of the tentative net capital of the security-based swap dealer. A security-based swap dealer may use the credit risk standards of paragraph (d) to compute a deduction for credit risk for security-based swap transactions that are subject to an initial margin exception set forth in § 240.18a–3(c)(1)(iii) instead of the provisions of paragraph (c)(1)(ix)(B)(1) of this section, and, for swap transactions instead of the provisions of paragraph (c)(1)(ix)(B)(2) of this section.

4. The 2012 Proposals included a capital charge for nonbank SBSDs when a counterparty requires initial margin to be segregated pursuant to Section 3E(f) of the Act, which among other things, provides that the collateral must be carried by an independent third-party custodian. Collateral held in this manner would not be in the possession or control of the nonbank SBSD, nor would it be capable of being liquidated promptly by the nonbank SBSD without the intervention of a third party. Commenters argued that the charge would discourage the use of segregation under Section 3E(f) of the Act, and that the charge would create costs to the affected nonbank SBSD (which would be passed on to customers), and that the parties could properly structure an agreement to address the Commission’s concern about the nonbank SBSD’s lack of control over the collateral. In light of the comments and the goals of this provision, the Commission requests comment on whether there should be an exception to taking the capital charge, (whether 100 percent (100%) or a credit risk charge, as applicable) under conditions that promote the SBSD’s ability to promptly access the collateral if needed. Should there be an exception with the following conditions: (1) The custodian is a bank; (2) the nonbank SBSD enters into an agreement with the custodian and the counterparty that provides the nonbank SBSD with the same control over the collateral as would be the case if the nonbank SBSD controlled the collateral directly; and (3) an opinion of counsel deems the agreement enforceable? The purpose of these conditions would be to provide the nonbank SBSD with the unfettered ability to access the collateral in the event the counterparty defaults and, thereby, promote the financial condition of the nonbank SBSD, particularly in a time of market distress. Would this be a practical exception? If not, please explain why.

b. The Commission is considering providing guidance on ways a nonbank SBSD could structure the account control agreement to meet a requirement that the nonbank SBSD have the same control over the collateral as would be the case if the nonbank SBSD controlled the collateral directly. In developing the guidance on ways this requirement could be met, the Commission asks commenters to address whether the agreement between the nonbank SBSD, counterparty, and the third-party custodian should: (1) Provide that the collateral will be released promptly and directed in accordance with the instructions of the nonbank SBSD upon the receipt of an effective notice from the nonbank SBSD; (2) provide that when the counterparty provides an effective notice to access the collateral the nonbank SBSD will have sufficient time to challenge the notice in good faith and that the collateral will not be released until a prior agreed-upon condition among the three parties has occurred; and (3) give priority to an effective notice from the nonbank SBSD over an effective notice from the counterparty, as well as priority to the nonbank SBSD’s instruction about how to transfer the collateral in the event the custodian terminates the account control agreement? Are there any other provisions regarding the account control agreement that the Commission should address to assist nonbank SBSDs in structuring the agreements to meet a requirement in a rule that the nonbank SBSD have the same control over the collateral as would be the case if the nonbank SBSD controlled the collateral directly?

c. The potential modification to the rule text in the 2012 Proposals
discussed above in 4.a would establish conditions under which a nonbank SBSD could avoid the capital charge that applies when a counterparty requires initial margin to be segregated pursuant to Section 3E(f) of the Act. Would rule language as described below affect this potential modification to the rule text in the 2012 Proposals? If not, please explain why and suggest alternative rule language. If the Commission were to use the language described below, would it strike an appropriate balance in terms of achieving the objectives of the proposed rule and addressing the commenters’ concerns about the impact of the capital charge? If not, please explain why and suggest alternative rule language that could more effectively and efficiently strike the balance and achieve the objective.

The potential modifications to paragraph (c)(2)(x)(B) of Rule 15c3–1 would provide the following deductions from net worth in lieu of collecting collateral for security-based swap and swap transactions: (1) Security-based swaps. Deducting the amounts calculated pursuant to § 240.18a–3(c)(1)(i)(B) for the account of a counterparty at the broker or dealer that is subject to an initial margin exception set forth in § 240.18a–3(c)(1)(iii), less the margin value of collateral held in the account of the counterparty at the broker or dealer. (2) Swaps. Deducting the initial margin calculated pursuant to § 240.18a–3(d)(2) for swaps other than equity swaps, or § 240.15c3–1b, as applicable, in the account of a counterparty at the broker or dealer, less the margin value of collateral held in the account of the counterparty at the broker or dealer. (3) Treatment of collateral held at a third-party custodian. For the purposes of the deductions required pursuant to paragraphs (c)(1)(ix)(B)(1) and (2) of this section, collateral held by an independent third-party custodian as initial margin pursuant to Section 3E(f) of the Act or Section 4s(l) of the Commodity Exchange Act may be treated as collateral held in the account of the counterparty at the broker or dealer if: (a) The independent third-party custodian is a bank as defined in Section 3(a)(6) of the Act that is not affiliated with the counterparty; (b) The broker or dealer, the independent third-party custodian, and the counterparty that delivered the collateral to the custodian have executed an account control agreement governing the terms under which the custodian holds and releases collateral pledged by the counterparty as initial margin that provides the broker or dealer with the same control over the collateral as would be the case if the broker or dealer controlled the collateral directly; and (c) The broker or dealer obtains a written opinion from outside counsel that the account control agreement is legally valid, binding, and enforceable in all material respects, including in the event of bankruptcy, insolvency, or a similar proceeding.  

5. The 2012 Proposals noted that a nonbank SBSD would need to deduct from net worth the value of initial margin delivered to a counterparty when computing net capital. A comment letter encouraged the Commission to provide a means for nonbank SBSDs to post initial margin to SBSDs and other types of counterparties without incurring the capital charge. If the Commission adopts capital and margin rules applicable to SBSDs, should the Commission provide a means for a nonbank SBSD to avoid this deduction if the following conditions are met: (1) The initial margin requirement is funded by a fully executed written loan agreement with an affiliate of the broker-dealer; (2) the loan agreement provides that the lender waives re-payment of the loan until the initial margin is returned to the broker-dealer; and (3) the broker-dealer’s liability to the lender can be fully satisfied by delivering the collateral serving as initial margin to the lender? A Commission action providing this relief would be styled after the Staff Letter. Would this approach provide a practical solution with respect to avoiding this capital charge? If not, please explain why. Should the Commission by rule permit this approach? Are there alternatives that would more effectively and efficiently achieve this objective? If so, what are they?

Margin

6. The 2012 Proposals included a provision that would require a nonbank SBSD to calculate a daily initial margin amount for each counterparty. The nonbank SBSD could use the standardized or model-based deductions provided by a swap dealer or other counterparty.
prescribed in the proposed capital rule for nonbank SBSDs to calculate the initial margin amount, except that initial margin for equity security-based swaps would need to be determined exclusively using the standardized deductions.

Some commenters argued that the Commission should approve a uniform initial margin model because it would reduce counterparty disputes and increase efficiency.\(^40\) Since the publication of the 2012 Proposals, the prudential regulators and the CFTC adopted final margin rules that permit the use of a model to calculate initial margin subject to the approval of the CFTC or a firm’s prudential regulator.\(^41\) The Commission understands that the firms subject to these final rules have widely adopted the use of an industry-developed uniform model to compute initial margin,\(^42\) in light of the comments and the goals of this provision, the Commission requests comment on whether the margin rule should permit nonbank SBSDs to apply to use models other than proprietary capital models to compute initial margin, including applying to use a standard industry model. The purpose would be to provide flexibility to nonbank SBSDs to apply to the Commission for authorization to use a proprietary or other model to compute initial margin, and, with respect to an industry standard model, to increase transparency and decrease margin disputes among counterparties.

Would rule language as described below effect this potential modification to the rule text in the 2012 Proposals? If not, please explain why and suggest alternative rule language. If the Commission were to use the language described below, would it strike an appropriate balance in terms of achieving the objectives of the proposed rule and addressing commenters’ requests for more flexibility? If not, please explain why and suggest alternative rule language that could more effectively and efficiently strike the balance and achieve the objective.

The potential modifications to paragraph (d)(2)(i) of Rule 18a–3 would provide: For security-based swaps other than equity security-based swaps, a security-based swap dealer may apply to the Commission for authorization to use a model to compute the margin amount required by paragraph (c)(1)(i)[B] of this section and to compute the deductions required by paragraph § 240.15c3–1(c)(2)[xvi] or § 240.18a–1(c)(1)[ix], as applicable, subject to the application process in § 240.15c3–1 or § 240.18a–1(d), as applicable. The model must use a ninety-nine percent (99%) confidence level with price changes equivalent to a ten business-day movement in rates and prices, and must use risk factors sufficient to cover all the material price risks inherent in the position for which the margin amount or deductions are being calculated, including foreign exchange or interest rate risk, credit risk, equity risk, and commodity risk, as appropriate. Empirical correlations may be recognized by the model within each broad risk category, but not across broad risk categories.

7. The 2012 Proposals included a requirement that a nonbank SBSD would need to collect initial and variation margin from each counterparty unless an exception applies.\(^43\) The proposed rule contained four exceptions under which variation and/or initial margin need not be collected: (1) When the counterparty is a commercial end user; (2) when the counterparty is another SBSD; (3) when the counterparty requires segregation pursuant to Section 3E(f) of the Act; and (4) when the counterparty’s account holds only legacy transactions.\(^44\) Some commenters encouraged the Commission to adopt a threshold below which initial margin need not be collected and noted that the prudential regulators and the CFTC established a $50 million threshold (consistent with the recommendation of an international standard setting body).\(^45\) In light of the comments and the goals of this provision, the Commission requests comment on whether it would be appropriate to establish a risk-based threshold. A fixed-dollar threshold, depending on the size and activities of the nonbank SBSD, could either be too large and, therefore, not adequately address the risk, or too small and, therefore, overcompensate for the risk. Should a risk-based threshold take into account the financial condition of the SBSD and the counterparty by providing that initial margin need not be collected from a counterparty when the amount is less than one percent (1%) or some other percent of a nonbank SBSD’s tentative net capital\(^46\) and is less than ten percent (10%) or some other percent\(^47\) of the counterparty’s net worth (in which case, only the amount above the threshold would need to be collected)? The purpose of these financial metrics would be to establish a threshold that is scalable and has a more direct relation to the risk to the nonbank SBSD arising from its security-based swap activities.

Would rule language as described below effect this potential modification to the rule text in the 2012 Proposals? If not, please explain why and suggest alternative rule language. If the Commission were to use the language described below, would it strike an appropriate balance in terms of achieving the objectives of the proposed rule and addressing commenters’ requests for a threshold? If not, please explain why and suggest alternative rule language that could more effectively and efficiently strike the balance and achieve the objective.

The potential modifications to paragraph (c)(1)[iii][E] of Rule 18a–3 would provide that an SBSD may elect not to collect the amount required under paragraph (c)(1)[ii][B] of this section to the extent that the amount does not exceed the lesser of: (1) 1 percent (1%) of the security-based swap dealer’s tentative net capital; or (2) ten percent (10%) of the net worth of the counterparty.

8. As noted above, the 2012 Proposals included an exception from collecting margin when the counterparty is another SBSD.\(^48\) In particular, the Commission proposed two alternatives with respect to SBSD counterparties.\(^49\) Under the first alternative, a nonbank SBSD would not need to collect initial margin if the counterparty is another SBSD (“Alternative A”). This approach is consistent with the broker-dealer margin rules, which generally do not require a broker-dealer to collect margin


\(^{43}\) See, e.g., id.; ISDA, ISDA SIMM™ Deployed Today; New Industry Standard for Calculating Initial Margin Widely Adopted by Market Participants, 80 FR 74840: Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 81 FR 636.

\(^{44}\) See, e.g., id.; ISDA, ISDA SIMM™ Deployed Today; New Industry Standard for Calculating Initial Margin Widely Adopted by Market Participants, 80 FR 74840: Margin Requirements for Uncleared Swaps for Swap Dealers and Major Swap Participants, 81 FR 636.

\(^{45}\) See 2012 Proposals, 77 FR at 70263–69.

\(^{46}\) See 2012 Proposals, 77 FR at 70267–68.

\(^{47}\) See id.
from another broker-dealer. Under the proposed second alternative, a nonbank SBSD would be required to collect initial margin from another SBSD and the initial margin would need to be segregated pursuant to Section 3E(f) of the Act ("Alternative B").

A commenter argued that Alternative A was the preferred approach because requiring SBSDs to collect initial margin from other SBSDs would curtail the use of non-cleared security-based swaps for hedging, which would disrupt key financial services, such as those that facilitate the availability of home loans and corporate finance. This commenter also argued that the requirement to collect initial margin from another SBSD would have detrimental pro-cyclical effects because it would increase collateral demands in times of market stress. Other commenters supported Alternative B stating that Alternative A would permit an inappropriate build-up of systemic risk for transactions within the financial system.

a. The Commission requests comment and supporting data that would assist in the quantification of the economic impacts of Alternatives A and B. The 2012 Proposals discussed the potential for increased use of leverage, the potential for a nonbank SBSD to fail, and the potential that a default by a nonbank SBSD could translate to defaults of counterparty SBSDs. The 2012 Proposals also noted that the likelihood of these potential events occurring would be smaller under Alternative B than under Alternative A. Would the proposed capital requirements complement Alternative A to reduce the potential for increased use of leverage, the potential for a nonbank SBSD to fail, and the potential that a default by a nonbank SBSD could translate to a default of counterparty SBSDs caused by exposure to credit risk in inter-dealer positions? Would there be situations where the proposed capital requirements and Alternative A would not prevent a failure of a nonbank SBSD caused by security-based swap trading losses? Would there be situations where the proposed capital requirements and Alternative A would avoid a failure of a nonbank SBSD by not imposing pro-cyclical collateral demands?

The 2012 Proposals also noted that in comparison to Alternative A or current practices, Alternative B could have a more significant negative impact on the liquidity of nonbank SBSDs and their ability to trade in security-based swaps. If Alternative B is adopted, how much initial margin would be segregated at third-party custodians and how would it impact the liquidity of nonbank SBSDs? If Alternative B is adopted, would the proposed margin requirements limit the ability of nonbank SBSDs to trade in security-based swaps?

Finally, the 2012 Proposals noted that depending on whether Alternative A or B is adopted, the proposed margin requirements may create the potential for regulatory arbitrage. In particular, the 2012 Proposals noted that if the Commission does not require nonbank SBSDs to collect initial margin in their inter-dealer transactions (as proposed in Alternative A), while the prudential regulators require the collection of initial margin for the same transactions, intermediaries could have an incentive to conduct business through nonbank entities. Would Alternative A create more opportunities for regulatory arbitrage than Alternative B, and would these regulatory arbitrage opportunities have a significant economic impact? If so, please explain how. In addition, Alternative A would differ in some respects from an international policy framework establishing recommended minimum standards for margin requirements for non-centrally cleared derivatives. Would these or other differences create opportunities for regulatory arbitrage, impede transactions with other market participants, or have an impact on substituted compliance determinations?

b. If Alternative A is adopted, should the exception apply to a broader class of entities than just other SBSDs? Should it apply if the nonbank SBSD’s counterparty is an SBSD, broker-dealer, bank, futures commission merchant, foreign bank, or foreign dealer? The purpose of adopting Alternative A with a modification to apply the exception to a broader class of counterparties would be to promote the liquidity of nonbank SBSDs and other market participants by reducing the amount of capital they must post as initial margin to counterparties.

Would rule language as described below effect Alternative A with the potential modification to expand the range of entities from which initial margin need not be collected? If not, please explain why and suggest alternative rule language. If the Commission were to use the language described below, would it strike an appropriate balance in terms of promoting the liquidity of nonbank SBSDs and other market participants and addressing commenters’ concerns about building up systemic risk? If not, please explain why and suggest alternative rule language that could more effectively and efficiently strike the balance and achieve the objective.

The potential modifications to paragraph (c)(1)(iii)(B) of Rule 18a-3 would provide that the requirements of paragraph (c)(1)(iii)(B) of this section do not apply to an account of a counterparty that is a security-based swap dealer, swap dealer, broker or dealer, futures commission merchant, bank, foreign bank, or a foreign broker or dealer.

9. In response to the 2012 Proposals, commenters argued that the requirements adopted pursuant to Title VII of the Dodd-Frank Act should permit the portfolio margining of security-based swaps, swaps, and related positions. Portfolio margining of security-based swaps, swaps, and related positions can offer benefits to investors and the markets, including aligning margin requirements more closely with the overall risks of a customer’s portfolio. Further, portfolio margining may help to improve cash flows and liquidity, and reduce volatility.

a. The Commission requests comment on whether swaps should be permitted to be held in a security-based swap account at an entity that is registered as a broker-dealer, nonbank SBSD, and swap dealer to provide a means to portfolio margin security-based swaps with swaps and related cash market and listed options positions. The Commission also requests comment on whether security-based swaps should be permitted to be held in a swap account at an entity that is registered as an FCM, swap dealer, and nonbank SBSD to provide a means to portfolio margin security-based swaps with swaps and related futures positions.

b. The Commission requests comment on whether swaps should be permitted to be held in a security-based swap account at an entity that is registered as a broker-dealer, nonbank SBSD, and swap dealer to provide a means to portfolio margin security-based swaps with swaps and related cash market and listed options positions.
account at an entity that is registered as a nonbank SBSD and swap dealer (but not as a broker-dealer or FCM) to provide a means to portfolio margin security-based swaps and swaps in a security-based swap account. The Commission also requests comment on whether security-based swaps should be permitted to be held in a swap account at an entity that is registered as a swap dealer and SBSD (but not as an FCM or broker-dealer) to provide a means to portfolio margin security-based swaps and swaps in a swap account. If so, should such portfolio margining be subject to conditions similar to those set forth in the Commission’s exemptive order permitting portfolio margining of credit default swaps (e.g., conditions regarding subordination agreements and disclosures)? In either scenario identified in this paragraph, should the SBSD dually registered as a swap dealer be permitted to use a model to determine portfolio margin requirements for security-based swaps and swaps that reference equity securities, provided the accounts do not hold cash market equity and listed options positions? The Commission requests comment on how security-based swaps, swaps, cash market and listed options positions, and collateral held in a security-based swap account at an entity registered as a broker-dealer, nonbank SBSD, and swap dealer would be treated in a liquidation proceeding. The Commission requests comment on how security-based swaps, swaps, futures positions, and collateral held in a swap account at an entity registered as an FCM, swap dealer, and nonbank SBSD would be treated in a liquidation proceeding. Would the treatment be different if the entity was also registered as a broker-dealer? The Commission requests comment on how swaps and security-based swaps held in a security-based swap account at an entity registered as an SBSD and swap dealer would be treated in a liquidation proceeding and how security-based swaps and swaps held in a swap account at an entity registered as an SBSD and swap dealer would be treated in a liquidation proceeding. For each of the four scenarios described above, what steps should be taken to provide protections to the account holders? What rights (including rights under the bankruptcy laws) might account holders have to waive these rights? Should the rule require the nonbank SBSD to provide complete and accurate disclosures about the treatment of assets in a liquidation, bankruptcy, or similar proceeding under each of the scenarios described above so that accountholders and prospective accountholders can make informed decisions about the type of portfolio margin account they want to use and about waiving any rights with respect to the account? 

d. The scenarios described above include permitting: (1) An entity registered as a broker-dealer, nonbank SBSD, and swap dealer to hold swaps in a security-based swap account to provide a means to portfolio margin security-based swaps with swaps and related cash market and listed options positions; and (2) an entity that is registered as an SBSD and swap dealer (but not as an FCM or broker-dealer) to hold swaps in a security-based swap account to provide a means to portfolio margin security-based swaps and swaps in a security-based swap account and to use a model to determine portfolio margin requirements for security-based swaps and swaps that reference equity securities, provided the accounts do not hold cash market equity and listed options positions.

Would rule language as described below effect these approaches to implement portfolio margining of swaps in a security-based swap account? If not, please explain why and suggest alternative rule language. If the Commission were to use the language described in this paragraph, would it strike an appropriate balance in terms of achieving the objectives of the proposed rules and addressing commenters’ requests to permit portfolio margining of swaps and security-based swaps? If not, please explain why and suggest alternative rule language that could more effectively and efficiently strike the balance and achieve the objective. The potential modifications to paragraph (a)(3) of Appendix A to Rule 18a–1 would provide: The term related instrument within an option class or product group refers to futures contracts, options on futures contracts, and securities, provided the accounts do not hold cash market equity and listed options positions.

The potential modifications to paragraph (a)(4) of Appendix A to Rule 18a–1 would provide: The term underlying instrument refers to long and short positions, as appropriate, covering the same foreign currency, the same security, and security future, security-based swap, or a security which is exchangeable for or convertible into the underlying security within a period of 90 days. If the exchange or conversion results in a loss upon conversion at the time when the security is deemed an underlying instrument for purposes of this Appendix A, the broker or dealer will deduct from net worth the full amount of the conversion loss. The term underlying instrument shall not be deemed to include securities options, futures contracts, options on futures contracts, qualified stock baskets, unlisted instruments (other than security-based swaps), or swaps.

The potential modifications to paragraph (d)(2)(iii) of Rule 18a–3 would provide: Notwithstanding paragraph (d)(2)(ii) of this section, a security-based swap dealer that is not registered as a broker or dealer pursuant to Section 15(b) of the Act (15 U.S.C. 78o(b)) may apply to the Commission for authorization to use a model to compute the margin amount required by paragraph (c)(1)(i)(B) of this section and to compute the deductions required by paragraph § 240.18a–1(c)(1)(ix) for equity security-based swaps and equity swaps, subject to the application process and model requirements of

paragraph (d)(2)(i) of this section; provided, however, the account of the counterparty subject to the requirements of this paragraph may not hold equity securities or listed options.

Segregation

10. Section 3E(f) of the Act provides that a counterparty to a non-cleared security-based swap with an SBSD can require that initial margin be segregated at a third-party custodian or waive segregation. The 2012 Proposals included a third alternative under which the initial margin for the non-cleared security-based swap could be held by the SBSD and subject to requirements modeled on the broker-dealer customer protection rule but tailored to security-based swaps ("omnibus segregation requirements"). The omnibus segregation requirements would be mandatory for initial margin held by the SBSD for cleared security-based swaps.

a. The Commission received a number of comments asking technical questions about how the proposed omnibus segregation requirements would operate in the context of security-based swap transactions, including specific questions about the computation of the reserve formula, and what types of hedging would be permitted under the proposed definition of "excess securities collateral." The Commission requests comment on whether there are aspects of the proposed omnibus segregation requirements where greater clarity regarding the application of the rule would be helpful. If so, please identify them and suggest appropriate modifications to the proposed rule.

b. The 2013 Proposals would treat segregation as a transaction-level requirement, and the Commission proposed paragraph (e) of Rule 18a–4 to prescribe the scope of application of the segregation requirements in Section 3E(f) of the Act and Rule 18a–4. The proposed cross-border application of these segregation requirements to a foreign SBSD or foreign MSBSP depends on whether it is a registered broker-dealer, a U.S. branch or agency of a foreign bank, or neither of the above, and whether the security-based swaps are cleared or non-cleared. The Commission requests comment on whether there are aspects of the proposed cross-border application of the segregation requirements where greater clarity regarding the application of the rule would be helpful. If so, please identify them and suggest appropriate modifications to the proposed rule.

c. The 2013 Proposals provided that a foreign SBSD that is a U.S. branch or agency of a foreign bank must comply with segregation requirements with respect to security-based swap transactions with U.S. security-based swap customers, but not with foreign security-based swap customers. Should the segregation requirements apply to certain foreign security-based swap customers? In particular, the Commission requests comment on whether a foreign SBSD that is not a broker-dealer and is a foreign bank should be required to comply with the segregation requirements (1) with respect to U.S. security-based swap customers (regardless of which branch or agency the customer’s transactions arise out of), and (2) with respect to a foreign security-based swap customer if the foreign SBSD holds funds or other property arising out of a transaction had by such person with a U.S. branch or agency of the foreign SBSD.

11. The Commission received a comment that the broker-dealer customer protection rule (Rule 15c3–3) should be amended to take into account margin that is posted at a clearing agency by broker-dealers not registered as SBSDs. The Commission requests comment on whether Rule 15c3–3 should be amended to add a new paragraph (p) and a new Exhibit B that would contain segregation requirements and a customer reserve formula that parallel those in proposed Rule 18a–4. The security-based swap segregation requirements that would be added to Rule 15c3–3 would be substantially the same as the requirements in each paragraph of proposed Rule 18a–4.

The purpose would be to permit broker-dealers that are not registered as SBSDs but that engage in security-based swap activities to use segregation requirements that parallel those in proposed Rule 18a–4 and which are tailored to security-based swaps. In addition, the purpose would be to locate in Rule 15c3–3 the security-based swap segregation requirements for entities registered as a broker-dealer and SBSD. Proposed Rule 18a–4 would apply to SBSDs that are not registered as broker-dealers.

12. The 2012 Proposals include a definition of "excess securities collateral" to identify securities and money market instruments received from security-based swap customers that must be held in physical possession or control. In particular, securities and money market instruments that are not being used to collateralize the SBSD's current exposure to the customer (i.e., exceed the variation margin requirement) would need to be in the physical possession or control of the SBSD unless one of two exceptions applies. The exceptions are that the securities and money market instruments are held in an account maintained with the SBSD and (1) the account is for non-cleared security-based swap customers, but not with foreign security-based swap customers; and (2) the account is for a non-cleared security-based swap customer, but only to the extent they are being used to meet a margin requirement of the clearing agency or other SBSD. Under the proposal, an SBSD could include as a debit item in the formula cash collateral posted to a clearing agency or another SBSD under the same circumstances as the exceptions to the definition of "excess securities collateral." The prudential regulators require initial margin posted by an SBSD to a bank SBSD to be held at a third-party custodian (rather than being held directly by the bank SBSD). This means that if an SBSD enters into a transaction with a bank SBSD to hedge a non-cleared security-based swap transaction with a security-based swap customer, the SBSD may have to post initial margin to the bank SBSD and that initial margin would need to be held by a third-party custodian rather than directly by the bank SBSD.

The Commission requests comment on when initial margin posted by an SBSD to a bank SBSD to hedge a transaction with a security-based swap customer should be treated for purposes of the possession or control and customer reserve requirements in the
proposed SBSD segregation rule. For purposes of the possession or control and customer reserve account requirements, should the initial margin be treated similarly to how initial margin an SBSD posts to a nonbank SBSD is treated if the purpose is to enter into a transaction that hedges a transaction with a security-based swap customer? The purpose would be to accommodate an SBSD that elects to enter into a hedging transaction with a bank SBSD and must post initial margin that is segregated at a third-party custodian.

Would rule language as described below effect this potential modification to the rule text in the 2012 Proposals? If not, please explain why and suggest alternative rule language. If the Commission were to use the language described below, would it strike an appropriate balance in terms of achieving the objectives of the proposed rule and accommodating SBSDs that elect to hedge a non-cleared security-based swap transaction by entering into an off-setting transaction with a bank SBSD? If not, please explain why and suggest alternative rule language that could more effectively and efficiently strike the balance and achieve the objective.

The potential modifications to paragraph (p)(1)(ii) of Rule 15c3–3 would provide: The term *excess securities collateral* means securities and money market instruments carried for the account of a security-based swap customer that have a market value in excess of the current exposure of the broker or dealer (after reducing the current exposure by the amount of cash in the account) to the security-based swap customer, excluding: (A) Securities and money market instruments held in a qualified clearing agency account by only to the extent the securities and money market instruments are being used to meet a margin requirement of the clearing agency resulting from a security-based swap transaction of the security-based swap customer; and (B) securities and money market instruments held in a qualified registered security-based swap dealer account or in a third-party custodial account but only to the extent the securities and money market instruments are being used to meet a regulatory margin requirement of a security-based swap dealer resulting from the security-based swap dealer entering into a non-cleared security-based swap transaction with the other security-based swap dealer to offset the risk of a non-cleared security-based swap transaction between the security-based swap dealer and the security-based swap customer.

The potential modifications to paragraph (p)(1)(viii) of Rule 15c3–3 would provide: The term *third-party custodial account* means an account carried by an independent third-party custodian that meets the following conditions: (A) The account is established for the purposes of meeting regulatory margin requirements of another security-based swap dealer; (B) The account is carried by a bank; (C) The account is designated for and on behalf of the broker or dealer for the benefit of its security-based swap customers and the account is subject to a written acknowledgement by the bank provided to and retained by the broker or dealer that the funds and other property held in the account are being held by the bank for the exclusive benefit of the security-based swap customers of the broker or dealer and and are being kept separate from any other accounts maintained by the broker or dealer with the bank; and (D) The account is subject to a written contract between the broker or dealer and the bank which provides that the funds and other property in the account shall at no time be used directly or indirectly as security for a loan or other extension of credit to the security-based swap dealer by the bank and, shall be subject to no right, charge, security interest, lien, or claim of any kind in favor of the bank or any person claiming through the bank.

The potential modifications to Line 16 of Exhibit B to Rule 15c3–3 would provide: Margin related to non-cleared security-based swap transactions in accounts carried for security-based swap customers and required and held in a qualified registered security-based swap dealer account at another security-based swap dealer or at a third-party custodial account.

The potential modifications to paragraph (a)(2) of Rule 18a–4 would provide: The term *excess securities collateral* means securities and money market instruments carried for the account of a security-based swap customer that have a market value in excess of the current exposure of the security-based swap dealer (after reducing the current exposure by the amount of cash in the account) to the security-based swap customer, excluding (i) securities and money market instruments held in a qualified clearing agency account but only to the extent the securities and money market instruments are being used to meet a margin requirement of the clearing agency resulting from a security-based swap transaction of the security-based swap customer; and (ii) securities and money market instruments held in a qualified registered security-based swap dealer account or in a third-party custodial account but only to the extent the securities and money market instruments are being used to meet a regulatory margin requirement of another security-based swap dealer resulting from the security-based swap dealer entering into a non-cleared security-based swap transaction with the other security-based swap dealer to offset the risk of a non-cleared security-based swap transaction between the security-based swap dealer and the security-based swap customer.

The potential modifications to paragraph (a)(10) of Rule 18a–4 would also provide: The term *third-party custodial account* means an account carried by an independent third-party custodian that meets the following conditions: (i) The account is established for the purposes of meeting regulatory margin requirements of another security-based swap dealer; (ii) The account is carried by a bank; (iii) The account is designated for and on behalf of the security-based swap dealer for the benefit of its security-based swap customers and the account is subject to a written acknowledgement by the bank provided to and retained by the security-based swap dealer that the funds and other property held in the account are being held by the bank for the exclusive benefit of the security-based swap customers of the security-based swap dealer and are being kept separate from any other accounts maintained by the security-based swap dealer with the bank; and (iv) The account is subject to a written contract between the security-based swap dealer and the bank which provides that the funds and other property in the account shall at no time be used directly or indirectly as security for a loan or other extension of credit to the security-based swap dealer by the bank and, shall be subject to no right, charge, security interest, lien, or claim of any kind in favor of the bank or any person claiming through the bank.

The potential modifications to Line 14 of Exhibit A to Rule 18a–4 would provide: Margin related to non-cleared security-based swap transactions in accounts carried for security-based swap customers and required and held in a qualified registered security-based swap dealer account at another security-based swap dealer or at a third-party custodial account.

13. The 2012 Proposals required an SBSD to deduct the amount of funds held in a security-based swap customer reserve account at a single bank to the extent the amount exceeds ten percent (10%) of the equity capital of the bank.
The potential modifications to paragraph (p)(3)(i) of Rule 15c3–3 would provide: In determining the amount maintained in a special reserve account for the exclusive benefit of security-based swap customers, the security-based swap dealer must deduct (A) the amount of cash deposited with a single non-affiliated bank to the extent the amount exceeds fifteen percent (15%) of the equity capital of the bank as reported by the bank in its most recent Call Report or any successor form of the bank; and (B) the total amount of cash deposited with an affiliated bank.

Similarly, the potential modifications to paragraph (c)(1)(i) of Rule 18a–4 would provide: In determining the amount maintained in a special reserve account for the exclusive benefit of security-based swap customers, the security-based swap dealer must deduct (A) the amount of cash deposited with a single non-affiliated bank to the extent the amount exceeds fifteen percent (15%) of the equity capital of the bank as reported by the bank in its most recent Call Report or any successor form of the bank; and (B) the total amount of cash deposited with an affiliated bank.

The potential modifications to paragraph (c)(1)(ii) of Rule 18a–4 would provide: In determining the amount maintained in a special reserve account for the exclusive benefit of security-based swap customers, the security-based swap dealer must deduct (A) the amount of cash deposited with a single non-affiliated bank to the extent the amount exceeds fifteen percent (15%) of the equity capital of the bank as reported by the bank in its most recent Call Report or any successor form of the bank; and (B) the total amount of cash deposited with an affiliated bank.

Substituted Compliance

14. The 2013 Proposals would make substituted compliance with respect to capital and margin requirements available to foreign nonbank SBSDs that are not also registered as broker-dealers. Upon a Commission substituted compliance determination, should the Commission consider whether the capital requirements of the foreign financial regulatory system are designed to help ensure the safety and soundness of registrants in a manner that is comparable to the proposed capital requirements for nonbank SBSDs? In addition, the proposed nonbank SBSD capital rules require nonbank SBSDs to maintain liquid assets in excess of the amount of the firm’s unsubordinated liabilities. In terms of the conditions that might be included in an order making an affirmative substituted compliance determination, should the Commission consider a condition that requires nonbank SBSDs relying on the order to maintain liquid assets in excess of their unsubordinated liabilities?

section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813)); and (B) for a security-based swap dealer for which there is not a prudential regulator, the total amount of cash deposited with an affiliated bank.

The potential modifications to paragraph (c)(1)(ii) of Rule 18a–4 would provide: In determining the amount maintained in a special reserve account for the exclusive benefit of security-based swap customers, the security-based swap dealer must deduct (A) the amount of cash deposited with a single non-affiliated bank to the extent the amount exceeds fifteen percent (15%) of the equity capital of the bank as reported by the bank in its most recent Call Report or any successor form of the bank; and (B) the total amount of cash deposited with an affiliated bank.

The proposed nonbank SBSD capital rules require nonbank SBSDs to maintain liquid assets in excess of the amount of the firm’s unsubordinated liabilities. In terms of the conditions that might be included in an order making an affirmative substituted compliance determination, should the Commission consider a condition that requires nonbank SBSDs relying on the order to maintain liquid assets in excess of their unsubordinated liabilities? Are there

82 See 2012 Proposals, 77 FR at 70221–25. 83 See, e.g., Interpreta-

c section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813)); and (B) for a security-based swap dealer for which there is not a prudential regulator, the total amount of cash deposited with an affiliated bank.

Substituted Compliance

14. The 2013 Proposals would make substituted compliance with respect to capital and margin requirements available to foreign nonbank SBSDs that are not also registered as broker-dealers. Upon a Commission substituted compliance determination, this type of SBSD would be available to satisfy relevant capital and margin requirements by complying with corresponding requirements under a foreign regulatory system. The Commission requests comment on whether the potential modifications to the rule text in the 2012 Proposals discussed in this release would have an impact on substituted compliance determinations. If so, please explain how.

A number of commenters requested that the Commission consider consistency with the prudential regulators, international standards, and foreign regulators when making substituted compliance determinations with respect to the proposed nonbank SBSD capital requirements. Commenters generally requested additional guidance regarding the criteria the Commission would consider when making substituted compliance determinations. In light of the comments and the goals of this provision, the Commission requests comment on the factors it should consider in making a substituted compliance determination with respect to the proposed nonbank SBSD capital requirements of Section 15F(e) of the Act and proposed Rule 18a–1. In making a substituted compliance determination, should the Commission consider whether the capital requirements of the foreign financial regulatory system are designed to help ensure the safety and soundness of registrants in a manner that is comparable to the proposed capital requirements for nonbank SBSDs? In addition, the proposed nonbank SBSD capital rules require nonbank SBSDs to maintain liquid assets in excess of the amount of the firm’s unsubordinated liabilities. In terms of the conditions that might be included in an order making an affirmative substituted compliance determination, should the Commission consider a condition that requires nonbank SBSDs relying on the order to maintain liquid assets in excess of their unsubordinated liabilities? Are there


Substituted Compliance

14. The 2013 Proposals would make substituted compliance with respect to capital and margin requirements available to foreign nonbank SBSDs that are not also registered as broker-dealers. Upon a Commission substituted compliance determination, this type of SBSD would be available to satisfy relevant capital and margin requirements by complying with corresponding requirements under a foreign regulatory system. The Commission requests comment on whether the potential modifications to the rule text in the 2012 Proposals discussed in this release would have an impact on substituted compliance determinations. If so, please explain how.

A number of commenters requested that the Commission consider consistency with the prudential regulators, international standards, and foreign regulators when making substituted compliance determinations with respect to the proposed nonbank SBSD capital requirements. Commenters generally requested additional guidance regarding the criteria the Commission would consider when making substituted compliance determinations. In light of the comments and the goals of this provision, the Commission requests comment on the factors it should consider in making a substituted compliance determination with respect to the proposed nonbank SBSD capital requirements of Section 15F(e) of the Act and proposed Rule 18a–1. In making a substituted compliance determination, should the Commission consider whether the capital requirements of the foreign financial regulatory system are designed to help ensure the safety and soundness of registrants in a manner that is comparable to the proposed capital requirements for nonbank SBSDs? In addition, the proposed nonbank SBSD capital rules require nonbank SBSDs to maintain liquid assets in excess of the amount of the firm’s unsubordinated liabilities. In terms of the conditions that might be included in an order making an affirmative substituted compliance determination, should the Commission consider a condition that requires nonbank SBSDs relying on the order to maintain liquid assets in excess of their unsubordinated liabilities? Are there
provide that substituted compliance is available with respect to: The capital requirements of Section 15F(e) of the Act (15 U.S.C. 78o–10(e) and § 240.18a–1; provided, however, that prior to making such substituted compliance determination with respect to security-based swap dealers, the Commission intends to consider (in addition to any conditions imposed) whether the capital requirements of the foreign financial regulatory system are designed to help ensure the safety and soundness of registrants in a manner that is comparable to the applicable provisions arising under the Act and its rules and regulations.

Compliance Date

15. In the Commission’s release establishing the registration process for SBSDs and MSBSPs, the Commission provided that the compliance date for the SBSD and MSBSP registration requirements will be the later of: Six months after the date of publication in the Federal Register of final rules establishing capital, margin, and segregation requirements for SBSDs and MSBSPs; the compliance date of final rules establishing recordkeeping and reporting requirements for SBSDs and MSBSPs; the compliance date of final rules establishing business conduct requirements under Sections 15F(h) and 15F(k) of the Exchange Act; or the compliance date for final rules establishing a process for a registered SBSD or MSBSP to make an application to the Commission to allow an associated person who is subject to a statutory disqualification to effect or be involved in effecting security-based swaps on the SBSD or MSBSP’s behalf (the “Registration Compliance Date”). Would this provide enough time for registrants to take the necessary steps to come into compliance with applicable requirements? If not, explain why. Would a longer period, such as 18 months after the date of publication of the last of four releases noted above in the Federal Register, be more appropriate? If so, explain why. Would a shorter period be more appropriate? If so, explain why. Should the Commission consider the timing of the phased implementation of initial margin requirements provided for by other regulators in making any changes to the compliance period? If so, explain why.

Additional Requests for Comment—Economic Implications

16. The Proposals contain economic analyses seeking to identify and consider the benefits and costs, including the effects on efficiency, competition and capital formation—that would result from the proposed capital, margin, and segregation requirements. To assist in the quantification of the economic effects of the proposed requirements, the Commission requests comment and supporting data on the current risk management practices that support the trading activity in security-based swaps. Specifically, what are the main sources of funding available to entities that would be registering as nonbank SBSDs to support their trading activity? How much of the capital available to an entity that would be registering as a nonbank SBSD consists of liquid capital? What are typical risk management procedures for dealing with losses stemming from the market risk of security-based swap positions? What are typical risk management procedures for dealing with losses stemming from the credit risk of uncle collateralized security-based swap positions? In the event that losses from trading activities overcome the available liquid capital, how are excess losses dealt with? What are the operational risks and concerns associated with maintaining adequate levels of capital? The Commission also requests comment and data on how the baseline of the economic analyses has changed since the publication of the Proposals. For example, in 2015, the U.S. prudential regulators and the CFTC adopted final rules on minimum margin requirements for non-cleared swaps that began to be implemented in September 2016. A June 2017 survey on dealer financing terms noted that some of the survey respondents indicated that their clients’ transaction volume or their own transaction volume in non-cleared swaps decreased somewhat over the period of September 2016 to June 2017. However, the respondents reported no changes in the prices that
they quote to their clients in non-cleared swaps over this period. One-fifth of the survey respondents also reported that they would be less likely to exchange daily variation margin with mutual funds, exchange-traded funds, pension plans, endowments, and separately managed accounts established with investment advisers due primarily to lack of operational readiness (e.g., the need to establish or update the necessary credit support annexes to cover daily exchange of variation margin) over this period. Two-fifths of the survey respondents also reported that the volume of mark and collateral disputes on variation margin has increased somewhat over this period. Furthermore, the survey noted that there is variation among respondents with respect to the number of days it takes to resolve a mark and collateral dispute on variation margin, with one-third reporting less than two days, while three-fifths reporting more than two days but less than a week, on average. This type of data could provide insight regarding how entities that may register as nonbank SBSDs may respond to the Commission’s final margin requirements.

Commenters are asked to describe changes, if applicable, in: (1) The trading volumes in the relevant security-based swap and swap markets; (2) the regulatory structure of these markets; and (3) the number and types of entities that participate in these markets. Commenters also are asked to describe how those changes in the baseline would impact the potential benefits and costs—including the effects on efficiency, competition and capital formation—of the Proposals as well as the potential benefits and costs—including the effects on efficiency, competition and capital formation—that would result from the potential alternatives described in the questions above taking the changes in the baseline into account (if applicable).

Finally, the Commission requests comment on whether there are economic considerations apart from those discussed in the Proposals that should be considered in the economic analysis of the capital, margin, and segregation requirements as well as the alternatives described in the questions above.

By the Commission.

Dated: October 11, 2018.

Eduardo A. Aleman,
Assistant Secretary.
[FR Doc. 2018–22531 Filed 10–18–18; 8:45 am]
Corps, or, in the case of the Coast Guard, the Judge Advocate General of the Coast Guard, about important new cases or important developments in pending cases related to such dependents; and (3) take additional steps that may be authorized under relevant international agreement(s) with the receiving State to implement the policy of this part.

Expected Impact of the Proposed Rule

The proposed revisions are expected to cause no change to the burden or cost to dependents of DoD personnel. DoD is not changing the process for dependents to access these services and therefore does not anticipate a change in the population of eligible DoD dependents for these services. The Department will continue to provide relevant free legal services to the dependents of DoD personnel and acceptance of these legal services is entirely voluntary.

Regulatory Procedures

Executive Order 12866, “Regulatory Planning and Review” and Executive Order 13563, “Improving Regulation and Regulatory Review”

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a “significant regulatory action,” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB) under the requirements of these Executive Orders.

Executive Order 13771, “Reducing Regulation and Controlling Regulatory Costs”

This proposed rule is not expected to be subject to the requirements of E.O. 13771 (82 FR 9339, February 3, 2017) because this proposed rule is expected to be related to agency organization, management, or personnel.


Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1532) requires agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. This proposed rule will not mandate any requirements for State, local, or tribal governments, nor will it affect private sector costs.


The Department of Defense certifies that this proposed rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Public Law 96–511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

It has been determined that 32 CFR part 151 does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, “Federalism”

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule will not have a substantial effect on State and local governments.

List of Subjects in 32 CFR Part 151

Courts, Foreign relations, Military personnel, Prisons.

Accordingly, 32 CFR part 151 is proposed to be revised to read as follows:

PART 151—FOREIGN CRIMINAL AND CIVIL JURISDICTION

Sec. 151.1 Purpose.
151.2 Applicability.
151.3 Definitions.
151.4 Policy.
151.5 Responsibilities.
151.6 Procedures.


§151.1 Purpose.

This rule establishes policy, assigns responsibilities, and prescribes procedures, supplemental to those provided in DoD Instruction 5525.01 “Foreign Criminal and Civil Jurisdiction,” which will be made available at http://www.esd.whs.mil/DirEcts/issuances/dodti/, concerning trial by foreign criminal courts of, treatment in foreign prisons of, and the payment of counsel fees in certain civil cases for the following individuals, referred to collectively in this rule as “dependents of DoD personnel,” when those individuals are in a foreign country as a result of accompanying DoD personnel who are assigned duty in that country:

(a) Command-sponsored and non-command sponsored dependents of Armed Forces members;
(b) Dependents of nationals and non-nationals of the United States who are serving with or accompanying the Military Services (referred to in this rule as “non-military DoD personnel”) in an area outside the United States and its territories and possessions, the Commonwealth of the Northern Mariana Islands, and the Commonwealth of Puerto Rico (referred to collectively in this rule as “outside the United States”);
(c) Dependents of DoD personnel serving under a U.S. Chief of Mission are not considered to be “dependents of DoD personnel” for the purposes of this rule.

§151.2 Applicability.

This part applies to the Office of the Secretary of Defense, the Military Departments (including the Coast Guard at all times, including when it is a Service in the Department of Homeland Security by agreement with that Department), the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD.

§151.3 Definitions.

These terms and their definitions are for the purposes of this part.


Designated commanding officer (DCO). The military officer who is designated by the appropriate geographic Combatant Commander to fulfill the duties outlined in this part.

Non-military DoD personnel. Nationals and non-nationals of the United States who are serving with or accompanying the Armed Forces in an area outside the United States and its territories and possessions, the northern Mariana Islands, and the Commonwealth of Puerto Rico.

DoD personnel. Armed Forces members and non-military DoD personnel serving...
under a U.S. Chief of Mission are not considered to be “DoD personnel” as defined in this part.

§151.4 Policy.

(a) The Department of Defense will, for dependents of DoD personnel when those dependents are in a foreign country accompanying DoD personnel who are assigned duty to that foreign country:

(1) Maximize the exercise of U.S. jurisdiction to the extent permissible under applicable status of forces agreements or other forms of jurisdiction arrangements.

(2) Protect, to the maximum extent possible, the rights of dependents of DoD personnel who may be subject to criminal trial by foreign courts and imprisonment in foreign prisons.

(3) Secure, where possible, the release of an accused to the custody of U.S. authorities pending completion of all foreign judicial proceedings.

(b) [Reserved]

§151.5 Responsibilities.

(a) The Secretaries of the Military Departments ensure the adequacy of regulations in establishing an information and education policy on the laws and customs of the host country for dependents of DoD personnel assigned to foreign areas.

(b) For each country in their respective assigned area of responsibility (AOR), the geographic Combatant Commanders:

(1) Oversee Command implementation of the procedures in this part.

(2) Oversee DCO responsibilities, as described in paragraphs (c)(1) through (c)(4) of this section.

(c) DCO responsibilities. The DCOs:

(1) Are responsible for formal invocation, where applicable, of the Senate resolution procedure in each foreign country where dependents of DoD personnel are present, consistent with the U.S. Senate Resolution of Ratification, with reservations, to the North Atlantic Treaty Organization Status of Forces Agreement, as agreed to by the Senate on July 15, 1953.

(2) In cooperation with the appropriate U.S. Chief of Mission and to the maximum extent possible, ensure dependents of DoD personnel receive the same treatment, rights, and support as Armed Forces members when in the custody of foreign authorities, or when confined (pre-trial and post-trial) in foreign penal institutions. DCOs will work with the appropriate U.S. Chief of Mission to make appropriate diplomatic contacts for dependents of DoD personnel who are not U.S. nationals.

(3) Report informally and immediately to the General Counsel of the Department of Defense, the applicable geographic Combatant Commander, and the General Counsel and the Judge Advocate General of the respective Military Department or, in the case of the U.S. Marine Corps (USMC), to the General Counsel of the Navy and the Staff Judge Advocate to the Commandant of the Marine Corps, or, in the case of the Coast Guard, the Judge Advocate General of the Coast Guard, about important new cases or important developments in pending cases. Important cases include, but are not limited to, instances of denial of the procedural safeguards under any applicable agreement; deficiency in the treatment or conditions of confinement in foreign penal institutions; or arbitrary denial of permission to visit dependents of DoD personnel.

(4) Take additional steps that may be authorized under relevant international agreements with the receiving State to implement the policy of this part.

§151.6 Procedures.

(a) Request to foreign authorities not to exercise their criminal and civil jurisdiction over dependents. The procedures in this section will be followed when it appears that foreign authorities may exercise criminal jurisdiction over dependents of DoD personnel:

(1) When the DCO determines, after a careful consideration of all the circumstances, including consultation with the Department of Justice where the matter involves possible prosecution in U.S. civilian courts, that suitable action can be taken under existing U.S. laws or administrative regulations, the DCO may request the local foreign authorities to waive the exercise of criminal jurisdiction.

(2) When it appears possible that the accused may not obtain a fair trial, the commander exercising general court-martial jurisdiction over the command to which such persons are attached or with which they are associated will communicate directly with the DCO, reporting the full facts of the case. The DCO will then determine, in the light of legal procedures in effect in that country, if there is a risk that the accused will not receive a fair trial. If the DCO determines that there is a risk that the accused will not receive a fair trial, the DCO will decide, after consultation with the U.S. Chief of Mission, whether a request should be submitted through diplomatic channels to foreign authorities seeking their assurances of a fair trial for the accused or, in appropriate circumstances, that they waive the exercise of jurisdiction over the accused. If the DCO so decides, a recommendation will be submitted through the geographic Combatant Commander and the Chairman of the Joint Chiefs of Staff to the Secretary of Defense. Copies must be provided to the Secretary concerned and the GC DoD.

(b) Trial observers and trial observers’ reports. (1) U.S. observers at trials before courts of the receiving country (referred to in this rule as “trial observers”) must attend and prepare formal reports in all cases of trials by foreign courts or tribunals of dependents of DoD personnel, except for minor offenses. In cases of minor offenses, the observer will attend the trial at the discretion of the DCO, but will not be required to make a formal report.

(i) Unless directed by the DCO, trial observers are not required to attend all preliminary proceedings, such as scheduling hearings, but will attend the trial on the merits and other pre- and post-trial proceedings where significant procedural or substantive matters are decided.

(ii) Trial observer reports regarding dependents of DoD personnel will be handled and processed pursuant to DoD Instruction 5525.01(4)(b–c).

(2) The DCO, upon receipt of a trial observer report, will be responsible for determining whether:

(i) There was any failure to comply with the procedural safeguards secured by the pertinent status of forces agreement.

(ii) The accused received a fair trial under all the circumstances. Due regard should be given to those fair trial rights listed in DoD Instruction 5525.01 “Foreign Criminal and Civil Jurisdiction,” Enclosure 5, “Fair Trial Guarantees” that are relevant to the particular facts and circumstances of the trial. A trial will not be determined to be unfair merely because it is not conducted in a manner identical to trials held in the United States.

(A) If the DCO believes that the procedural safeguards specified in pertinent agreements were denied or that the trial was otherwise unjust, the DCO will submit a recommendation as to appropriate action to rectify the trial deficiencies and otherwise to protect the rights or interests of the accused. This recommendation must include a statement of efforts taken or to be taken at the local level to protect the rights of the accused.

(B) The DCO will submit the recommendation to the Secretary of Defense, through the Under Secretary of Defense for Policy (with an advance copy to the General Counsel of the Department of Defense); copies must be
provided to the geographic Combatant Commander concerned, the General Counsel and the Judge Advocate General of the Military Department concerned or, in the case of the USMC, to the General Counsel of the Navy and the Staff Judge Advocate to the Commandant of the Marine Corps, or, in the case of the Coast Guard, the Judge Advocate General of the Coast Guard, and the Chairman of the Joint Chiefs of Staff.

(c) Counsel fees and related assistance for U.S. personnel not subject to the UCMJ. In cases of exceptional interest to the Military Department concerned or the Department of Homeland Security involving non-military DoD personnel, the Secretary of that Military Department or the Secretary of Homeland Security may approve, pursuant to 10 U.S.C. 1037, under the following circumstances:

(1) Criminal cases. Requests for the provision of counsel fees and payment of expenses in criminal cases may be approved in pre-trial, trial, appellate, and post-trial proceedings in any criminal case where:

(i) The sentence that is normally imposed includes confinement, whether or not such sentence is suspended;

(ii) Capital punishment might be imposed;

(iii) An appeal is made from any proceeding in which there appears to have been a denial of the substantial rights of the accused;

(iv) The case, although not within the criteria established in paragraphs (c)(1)(i) through (c)(1)(iii) of this section, is considered to have significant impact on U.S. interests, including upon the relations of the Armed Forces with the host country.

(2) Civil cases. Requests for provision of counsel fees and payment of expenses in civil cases may be granted in trial and appellate proceedings in civil cases where the case is considered to have a significant impact on the relations of the Armed Forces with the host country; or in cases brought against eligible non-military DoD personnel (and in exceptional cases, by such personnel) if the case is considered to involve any other U.S. interest.

(3) Funding restrictions. (i) No funds will be provided under this part in cases where the U.S. Government is—in actuality or in legal effect—the plaintiff or the defendant; all such cases shall be referred to the Department of Justice, Office of Foreign Litigation. No funds will be provided under this part in cases where the non-military DoD personnel member is a plaintiff without prior authorization of the Secretary of the Military Department concerned or the Secretary of Homeland Security. The provisions of this paragraph also are applicable to proceedings with civil aspects that are brought by eligible personnel as criminal cases in accordance with local law. Funds for the posting of bail or bond to secure the release of non-military DoD personnel from confinement will be used as provided by applicable Armed Force regulations.

(ii) No funds will be provided under paragraph (c)(2) of this section to a plaintiff who, if successful, will receive an award, in whole or in part, from the United States.

(iii) As provided for in 10 U.S.C. 1037, a person on whose behalf a payment is made under this provision is not liable to reimburse the United States for that payment, unless he or she is responsible for the forfeiture of bail provided for him or her under this provision.

(d) Treatment of dependents confined in foreign penal institutions. In cooperation with the appropriate U.S. Chief of Mission and to the maximum extent possible, military commanders will ensure that dependents of DoD personnel receive the same treatment, rights, and support as would be extended to Armed Forces members when in the custody of foreign authorities, or when confined (pretrial and post-trial) in foreign penal institutions. Commanders will work with the appropriate U.S. Chief of Mission to make appropriate diplomatic contacts for the categories of dependents described in this section who are not U.S. nationals.

(e) Information policy. The general public and the Congress must be provided promptly with the maximum information concerning status of forces matters that are consistent with the national interest. Information will be coordinated and provided to the public and the Congress in accordance with established procedures, including those in DoD Directive 5122.05, “Assistant Secretary of Defense for Public Affairs (ASD(PA))” (available at http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/512205_dodd_2017.pdf?ver=2017-08-07-125832-023), 32 CFR part 286, 32 CFR part 310, and DoD Instruction 5400.04, “Provision of Information to Congress” (available at http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/540004p.pdf).

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

RIN 1625–AA00

Safety Zone; NASA Activities, Gulf of Mexico, Galveston, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary, moving safety zone for all navigable waters within a 1000-yard radius of the National Aeronautics and Space Administration’s (NASA’s) crew module uprighting system test article while it is being tested in the territorial waters of the Gulf of Mexico off the coast of Galveston, TX. The safety zone is necessary to protect persons, vessels, and the marine environment from potential hazards created by vessels and equipment engaged in the crew capsule’s at-sea testing. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector Houston-Galveston or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before November 5, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0962 using the Federal eRulemaking Portal at https://www.regulations.gov. See the "Public Participation and Request for Comments" portion of the SUPPLEMENTARY INFORMATION section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Collin Sykes, Eighth Coast Guard District, Waterways Management Division, U.S. Coast Guard; telephone 504–671–2119, email Collin.T.Sykes@uscg.mil.

SUPPLEMENTARY INFORMATION:
The National Aeronautics and Space Administration’s (NASA’s) Orion program is evaluating an updated design to the crew module uprighting system (CMUS), the system of five airbags on top of the crew capsule that inflate upon splashdown. NASA tested the CMUS at the Neutral Buoyancy Lab at NASA’s Johnson Space Center in Houston, and requested Coast Guard support for the at-sea testing. The at-sea testing will involve numerous surface vessels, divers, and remote-operated submarine vehicles, and features a rapid rotation of the Orion test article in a confined area and partially controlled environment. Due to the complexity of the test and proximity of the participants, unauthorized access by persons or vessels outside the scope of the test present a significant hazard to human life, vessels, and government property. The Captain of the Port Sector Houston-Galveston (COTP) has determined that this rule is needed to protect persons, vessels, and the marine environment on the navigable waters within the safety zone during the test.

The purpose of this rulemaking is to ensure the safety of persons, vessels, and the marine environment on the navigable waters within a 1000-yard radius of the CMUS test article before, during, and after the scheduled testing activities.

The Coast Guard is issuing this notice of proposed rulemaking (NPRM) with a 15-day prior notice and opportunity to comment pursuant to section (b)(3) of the Administrative Procedure Act (APA) (5 U.S.C. 553). Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for publishing this NPRM with a 15-day comment period because it is impractical to provide a 30-day comment period. It is impracticable to publish an NPRM with a 30-day comment period because we must establish this temporary safety zone by November 28, 2018. A 15-day comment period would allow the Coast Guard to provide for public notice and comment, but also publish a rule, if adopted, soon enough that the length of the notice and comment period does not compromise public safety.

The Coast Guard is proposing to establish a temporary, moving safety zone that would cover all navigable waters within 1000 yards of NASA’s CMUS test article, which will be located in the territorial waters of the Gulf of Mexico off the coast of Galveston, TX. NASA anticipates that the testing activities will take place on approximately three days during the effective period, during daylight hours only. The effective period of this proposed rule covers a nine day window from November 28, 2018 through December 6, 2018, to allow for scheduling delays due to inclement weather or technical difficulties. On each of the approximately three days that the proposed rule would be enforced, the enforcement periods would begin approximately 2 hours before testing activities and last until approximately 2 hours after the testing activities. The COTP or a designated representative would inform the public through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Bulletins (MSIBs), and/or other means of public notice, as appropriate, at least 3 hours in advance of each enforcement period. Such notice of enforcement would also include more specific information regarding the location of the CMUS test article.

The duration of the proposed zone is intended to protect persons, vessels, and the marine environment on these navigable waters during the NASA testing activities. No vessel or person would be permitted to enter or remain in the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, and a Federal, State, and local officer designated by or assisting the COTP in the enforcement of the safety zone. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign “PATCOM”. Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16. All persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative. The COTP or a designated representative will inform the public of the enforcement times, dates, and locations, for this safety zone through BNMs, LNMs, and/or MSIBs, as appropriate. The regulatory text we are proposing appears at the end of this document.

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated as a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, and duration of the safety zone. Vessel traffic will be able to safely transit around this safety zone, which would affect a small, designated area off the coast of Galveston, TX, outside of the Houston Ship Channel and safety fairway during daylight hours on approximately three days. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 around the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule would not have a significant economic impact on a substantial number of small entities. While some owners or operators of vessels intending to transit the temporary safety zone may be small.
entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see ADDRESSES) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, 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. If you believe this proposed rule has implications for federalism or Indian tribes, you may contact the person listed in the FOR FURTHER INFORMATION CONTACT section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a temporary, moving safety zone that would prohibit entry within 1000 yards of the CMUS test article during daylight hours on approximately three days in the Gulf of Mexico. Normally, such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A Preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under ADDRESSES. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the FOR FURTHER INFORMATION CONTACT section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at http://www.regulations.gov. If your material cannot be submitted using http://www.regulations.gov, contact the person in the FOR FURTHER INFORMATION CONTACT section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to https://www.regulations.gov and will include any personal information you have provided. For more about privacy and the docket, visit https://www.regulations.gov/privacyNotice.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at http://www.regulations.gov and can be viewed by following that website’s instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:


2. Add § 165.T08–0962 to read as follows:

§ 165.T08–0962 Safety Zone; NASA Activities, Gulf of Mexico, Galveston, TX.

(a) Location. The following area is a safety zone: All navigable waters within 1,000 yards of the National Aeronautics and Space Administration’s (NASA’s) crew module uprighting system test article.

(b) Effective period. This section will be effective from November 28, 2018 through December 6, 2018.

(c) Enforcement periods. This section will be enforced on approximately 3 days during the effective period, during daylight hours. Each period of
enforcement will begin approximately 2 hours before testing activities and end approximately 2 hours after testing activities. The Captain of the Port Sector Houston-Galveston (COTP) or a designated representative will inform the public of the enforcement through Broadcast Notices to Mariner (BNMs), Local Notices to Mariner (LNMs), and/or Marine Safety Information Bulletins (MSIBs) or other means of public notice at least 3 hours in advance of the enforcement of this safety zone. Such notice of enforcement will also include more specific information regarding the location of the CMUS test article.

(d) Regulations. (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or a designated representative. A designated representative is a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, and a Federal, State, and local officer designated by or assisting the COTP in the enforcement of the safety zone. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign “PATCOM”.

(2) To seek permission to enter, contact the COTP or a designated representative by VHF Channel 16.

(3) If granted permission to enter, all vessels must transit at their slowest safe speed and comply with all lawful orders or directions of the COTP or a designated representative.

(e) Informational broadcasts. The COTP or a designated representative will inform the public through Broadcast Notices to Mariner (BNMs), Local Notices to Mariner (LNMs), and/or Marine Safety Information Bulletins (MSIBs) or other means of public notice of the enforcement period for the temporary safety zone as well as any changes in the dates and times of enforcement.

Kevin D. Oditt,
Captain, U.S. Coast Guard, Captain of the Port Sector Houston-Galveston.

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 63

[WC Docket No. 17–84; Report No. 3101]

Petition for Reconsideration of Action in Rulemaking Proceeding; Correction

AGENCY: Federal Communications Commission.

ACTION: Petition for Reconsideration; correction.

SUMMARY: The Federal Communications Commission (Commission) published a document in the Federal Register of September 19, 2018 (83 FR 47325), regarding a Petition for Reconsideration (Petition) filed in the Commission’s rulemaking proceeding. The document contained the incorrect deadline for filing replies to an opposition to the Petition. This document corrects the deadline for replies to an opposition to the Petition.

DATES: October 19, 2018.


FOR FURTHER INFORMATION CONTACT: Michele Berlove, Wireline Competition Bureau, at: (202) 418–1477; email: Michele.Berlove@fcc.gov.

SUPPLEMENTARY INFORMATION:

Correction

In the Federal Register of September 19, 2018, in FR Doc. 2018–20238, on page 47325, in the third column, and on page 47326 in the first column, correct the DATES section to read:

DATES: Oppositions to the Petition must be filed on or before October 4, 2018. Replies to an opposition must be filed on or before October 15, 2018.

Federal Communications Commission.
Marlene Dortch,
Secretary.

[FR Doc. 2018–22357 Filed 10–18–18; 8:45 am]
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

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, the United States Department of Agriculture’s (USDA) Rural Utilities Service (RUS) invites comments on this information collection for which the Agency intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by December 18, 2018.

FOR FURTHER INFORMATION CONTACT: Michele Brooks, Team Lead, Rural Development Innovation Center—Regulatory Team, USDA, 1400 Independence Avenue SW, STOP 1522, Room 5164, South Building, Washington, DC 20250–1522. Telephone: (202) 690–1078. Email: michele.brooks@wdc.usda.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget’s (OMB) regulation (5 CFR part 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 an information collection that RUS is submitting to OMB as a revision to an existing collection. 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 will have practical utility; (b) 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; (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 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. Comments may be sent to: Michele Brooks, Team Lead, Rural Development Innovation Center—Regulatory Team, USDA, 1400 Independence Avenue SW, STOP 1522, Room 5164, South Building, Washington, DC 20250–1522. Telephone: (202) 690–1078. Email: michele.brooks@wdc.usda.gov.

Title: 7 CFR part 1728, Electric Standards and Specifications for Materials and Construction.

OMB Control Number: 0572–0131.

Type of Request: Extension of a currently approved collection.

Abstract: RUS provides loans and loan guarantees in accordance with the Rural Electrification Act of 1936, 7 U.S.C. 901 et seq., as amended, (RE Act). Section 4 of the RE Act requires that the Agency make or guarantee a loan only if there is reasonable assurance that the loan, together with all outstanding loans and obligations of the Borrower, will be repaid in full within the time agreed. In order to facilitate the programmatic interests of the RE Act and, in order to assure that loans made or guaranteed by the Agency are adequately secure, RUS, as a secured lender, has established certain standards and specifications for materials, equipment, and the construction of electric systems. The use of standards and specifications for materials, equipment and construction units helps assure the Agency that: (1) Appropriate standards and specifications are maintained; (2) RUS loan security is not adversely affected, and; (3) Loan and loan guarantee funds are used effectively and for the intended purposes. The regulation, 7 CFR part 1728, establishes Agency policy that materials and equipment purchased by RUS Electric Borrowers or accepted as contractor-furnished material must conform to Agency standards and specifications where established and, if included in RUS Publication IP 202–1, “List of Materials Acceptable for Use on Systems of Agency Electrification Borrowers” (List of Materials), must be selected from that list or must have received technical acceptance from RUS.

Estimate of Burden: This collection of information is estimated to average 20 hours per response.

Respondents: Business or other for-profits.

Estimated Number of Respondents: 38.

Estimated Total Annual Burden on Respondents: 2,000 hours.

Copies of this information collection can be obtained from Robin M. Jones, Innovation Center, at (202) 772–1172, Email: robin.m.jones@wdc.usda.gov.

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.


Christopher A. McLean,
Acting Administrator, Rural Utilities Service.

[FR Doc. 2018–22824 Filed 10–18–18; 8:45 am]

BILLING CODE P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Sunshine Act Meeting

TIME AND DATE: October 24, 2018, 10:00 a.m. EDT.


STATUS: Open to the public.

MATTERS TO BE CONSIDERED: The Chemical Safety and Hazard Investigation Board (CSB) will convene a public meeting on Wednesday, October 24, 2018, at 10 a.m. EDT in Washington, DC, at the CSB offices located at 1750 Pennsylvania Avenue NW, Suite 910. The Board will discuss open investigations, the status of audits from the Office of the Inspector General, financial and organizational updates. New business will include an overview of items related to a new “Dust Hazards Perception Report,” a factual update on the CSB’s ongoing Kuraray investigation, and a discussion and possible vote on a policy regarding employee participation in CSB investigations.
Additional Information

The meeting is free and open to the public. If you require a translator or interpreter, please notify the individual listed below as the CONTACT PERSON FOR FURTHER INFORMATION, at least three business days prior to the meeting. A conference call line will be provided for those who cannot attend in person. Please use the following dial-in number to join the conference:

Dial In: 1 (630) 691–2748 Audience US Toll.

Confirmation Number: 47604548.

The CSB is an independent federal agency charged with investigating incidents and hazards that result, or may result, in the catastrophic release of extremely hazardous substances. The agency’s Board Members are appointed by the President and confirmed by the Senate. CSB investigations look into all aspects of chemical accidents and hazards, including physical causes such as equipment failure as well as inadequacies in regulations, industry standards, and safety management systems.

Public Comment

The time provided for public statements will depend upon the number of people who wish to speak. Speakers should assume that their presentations will be limited to three minutes or less, but commenters may submit written statements for the record.

CONTACT PERSON FOR MORE INFORMATION: Hillary Cohen, Communications Manager, at public@csb.gov or (202) 446–8094. Further information about this public meeting can be found on the CSB website at: www.csb.gov.


Raymond Porfiri,
Deputy General Counsel, Chemical Safety and Hazard Investigation Board.

CIVIL RIGHTS COMMISSION

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.


DATES: Friday, November 2, 2018, 9:00 a.m. ET.

ADDRESS: Place: National Place Building, 1331 Pennsylvania Ave. NW, 11th Floor, Suite 1150, Washington, DC 20245 (Entrance on F Street NW).

FOR FURTHER INFORMATION CONTACT: Brian Walch, (202) 376–8071; TTY: (202) 376–8116; publicaffairs@usccr.gov.

SUPPLEMENTARY INFORMATION: The U.S. Commission on Civil Rights will hold a public briefing to evaluate federal civil rights enforcement, examining in particular Fiscal Years 2016 through 2018. With this assessment, the Commission asks: What are the key elements for effective civil rights enforcement? Do federal agencies have sufficient resources to fulfill their enforcement responsibilities? Most importantly, is the federal government satisfying its obligation to the American people to protect and vindicate their civil rights, including in education, housing, healthcare, employment, policing, the justice system, and other areas?

Commissioners will hear from current and former senior federal government officials, academic and legal experts, and advocates. We will also offer an open comment session in which members of the public will be able to address the Commission (see below).

The Commission will issue a report from this investigation in fall 2019, including findings and recommendations. This briefing is open to the public.

The event will also live-stream at https://www.youtube.com/user/USCCR/videos. (Please note that streaming information is subject to change.) If attending in person, we ask that you RSVP to publicaffairs@usccr.gov. Persons with disabilities who need accommodation should contact Pamela Dunston at 202–376–8105 or at access@usccr.gov at least seven (7) business days before the date of the meeting.

We will offer an open comment session in which members of the public will be able to address the Commission. Detailed information on this open comment session will be announced on the Commission’s website (www.usccr.gov), Twitter (www.twitter.com/USCCRgov), and Facebook (www.facebook.com/USCCRgov) in advance of the briefing.

In addition, the Commission welcomes the submission of additional material for consideration as we prepare our report. Please submit such information to enforcement@usccr.gov no later than December 17, 2018.

Are Rights a Reality? Evaluating Federal Civil Rights Enforcement

Introductory Remarks: Chair Catherine E. Lhamon: 9:00 a.m.–9:10 a.m.

Panel One: Current and Former Federal Agency Officials, Larger Civil Rights Offices: 9:10 a.m.–10:40 a.m.

Panel Two: Current and Former Federal Agency Officials, Smaller Civil Rights Offices: 10:50 a.m.–12:10 p.m.

Panel Three: Advocates and Community Experts in Civil Rights Enforcement: 1:10 p.m.–2:30 p.m.

Panel Four: Academics and Legal Experts in Civil Rights Enforcement: 2:40 p.m.–4:00 p.m.

Open Public Comment Session: 5:00 p.m.–6:30 p.m.

Adjourn: 6:00 p.m.

Dated: October 17, 2018.

David Mussett,
Supervisory Chief, Regional Programs Unit.
Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over landline connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–888–364–3109 and providing the operator with the toll-free conference call-in number: 1–877–604–9665 and conference call ID: 5786008.

Members of the public are invited to submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, or emailed to Corrine Sanders at erq@uscrr.gov. Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at https://database.faca.gov/committee/meetings.aspx?cid=279, click the “Meeting Details” and “Documents” links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission’s website, www.uscrr.gov, or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda: Friday, November 2, 2018

I. Rollcall
II. Welcome
III. Planning Discussion
IV. Other Business

ACTION: Notice of suspension of program.

SUMMARY: This document serves as notice to state and local governments and to other federal agencies that beginning on January 1, 2019, the Bureau of the Census (Census Bureau) will suspend the Geographically Updated Population Certification Program for three years—the year preceding the decennial census, the decennial census year, and the year following it—to accommodate the 2020 Census operation. During this time, the Census Bureau will not provide the operations necessary to determine the updated April 1, 2010 census population and housing unit counts for entities that: Annex territory; incorporate or organize as counties; or incorporate or organize as boroughs, cities, towns, villages, townships, or other general purpose governments. However, the Census Bureau will consider all requests for population and housing count updates received in writing before January 1, 2019.

DATES: As of January 1, 2019, the Geographically Updated Population Certification Program will be suspended. It will remain suspended until December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Darryl Cohen, Population Division, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233, telephone (301) 763–2419, email Darryl.T.Cohen@census.gov.

SUPPLEMENTARY INFORMATION: The Census Bureau first began to make updated decennial census count determinations to reflect geographic boundary changes in 1972 in response to the requests of local governments to establish eligibility for participation in the General Revenue Sharing Program, authorized under Public Law 92–512. At that time, the Census Bureau established a fee-for-service program enabling entities with annexations to obtain updated decennial census population counts that reflected the population living in the annexed areas. The Census Bureau also received funding from the U.S. Department of the Treasury to make those determinations for larger annexations that met prescribed criteria and for new incorporations. The General Revenue Sharing Program ended on September 30, 1986, but the certification program continued into 1988 with support for the Census Bureau. The program was suspended to accommodate the 1990 Census operations and resumed in 1992. The Census Bureau supported the program through fiscal year 1995 for cities with large annexations and through fiscal year 1996 for new incorporated places. The program was continued on a fee-for-service basis only until June 1, 1998, at which time it was suspended for the 2000 Census (see the Federal Register, 63 FR 27706, May 20, 1998). In 2002, the program was resumed and has since been referred to as the Geographically Updated Population Certification Program or GUPCP (see the Federal Register, 67 FR 72095, December 4, 2002). As was the case for two previous censuses, the program was suspended to accommodate the 2010 Census operations (see the Federal Register, 72 FR 46602, August 21, 2007). The suspension began on January 1, 2008 and ended on December 31, 2012 (see the Federal Register, 78 FR 54863, September 6, 2013).

The Census Bureau is suspending the program for the year immediately preceding, the year of, and year following the 2020 Census to permit allocation of necessary resources to the decennial census. However, all requests for population and housing count updates received before January 1, 2019 will be considered. The Census Bureau will announce in a future Federal Register notice the date that the program will resume. The Census Bureau plans to resume the program in the year 2022, after 2020 Census data become available, for those entities that desire the service provided that any and all costs associated with this work are borne by the local governmental entity.

Authority to continue this program on a fee-for-service basis is contained in Title 13, United States Code, Section 8.


Ron S. Jarmin,
Deputy Director, Performing the Non-Exclusive Functions and Duties of the Director, Bureau of the Census.

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Luis Antonio Urdaneta Pozo, Inmate Number: 68375–018, FCI Edgefield, P.O. Box 725, Edgefield, SC 29824; Order Denying Export Privileges

On June 27, 2017, in the U.S. District Court for the Southern District of Florida, Luis Antonio Urdaneta Pozo (“Pozo”) was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778(2012)) (“AECA”). Specifically, Pozo was convicted of knowingly and willfully exporting from
the United States to Venezuela items designated as defense articles on the United States Munitions List, namely, handguns and ammunition of various calibers, without the required U.S. Department of State licenses. Pozo was sentenced to 63 months in prison, three years of supervised release, and a $100 special assessment.

Section 766.25 of the Export Administration Regulations (“EAR” or “Regulations”)¹ provides, in pertinent part, that “[t]he Director of the Office of Exporter Services, in consultation with the Director of the Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of . . . section 38 of the Arms Export Control Act (22 U.S.C. 2778).” 15 CFR 766.25(a). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d). In addition, Section 750.8 of the Regulations states that the Bureau of Industry and Security’s Office of Exporter Services may revoke any Bureau of Industry and Security’s (“BIS”) licenses previously issued pursuant to the Act or the Regulations in which the person had an interest at the time of his/her conviction.

BIS has received notice of Pozo’s conviction for violating Section 38 of the AECA, and has provided notice and an opportunity for Pozo to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has not received a submission from Pozo.

Based upon my review and consultations with BIS’s Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Pozo’s export privileges under the Regulations for a period of 10 years from the date of Pozo’s conviction. I have also decided to revoke all licenses issued pursuant to the Act or Regulations in which Pozo had an interest at the time of his conviction.

Accordingly, it is hereby ordered: First, from the date of this Order until June 27, 2027, Luis Antonio Urdaneta Pozo, with a last known address of Inmate Number: 68375–018, FCI Edgefield, P.O. Box 725, Edgefield, SC 29824, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (“the Denied Person”), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as “item”) exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;
B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or
C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:
A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;
B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;
C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;
D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or
E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States.

For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Pozo by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Pozo may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Pozo and shall be published in the Federal Register.

Sixth, this Order is effective immediately and shall remain in effect until June 27, 2027.

Issued this October 12, 2018.
Karen H. Nies-Vogel,
Director, Office of Exporter Services.

[FR Doc. 2018–22865 Filed 10–18–18; 8:45 am]
BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–830]

Carbon and Certain Alloy Steel Wire Rod From Mexico: Preliminary Affirmative Determination of Circumvention of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines
that imports of carbon and certain alloy steel wire rod (wire rod) with actual diameters less than 4.75 mm produced and/or exported by Deacero S.A.P.I. de C.V (Deacero) are circumventing the antidumping duty order on wire rod from Mexico.


SUPPLEMENTARY INFORMATION:

Background

On August 31, 2001, Co-Steel Raritan, Inc., GS Industries, Keystone Consolidated, Industries, Inc., and North Star Steel Texas, Inc. filed a petition seeking imposition of antidumping duties on imports of wire rod from Mexico.1 Following the completion of investigations and affirmative final determinations by Commerce and the U.S. International Trade Commission (ITC), Commerce issued an antidumping order on wire rod from Mexico (Order).2 On October 1, 2012, pursuant to section 781(c) of the Tariff Act of 1930, as amended (the Act), Commerce determined that wire rod with an actual diameter of 4.75 mm to 5.00 mm produced and/or exported to the United States by Deacero constituted merchandise altered in form or appearance in such minor respects that it should be included within the scope of the Order.3 On October 27, 2017, Nucor Corporation (a domestic interested party) (Nucor) filed a circumvention ruling request to determine whether wire rod with an actual diameter less than 4.75 mm produced and/or exported by Deacero to the United States is circumventing the Order.4 On February 7, 2018, pursuant to section 781(c) of the Act, Commerce initiated an anti-circumvention inquiry on wire rod with actual diameters that are less than 4.75 mm produced and/or exported by Deacero.5 For a complete description of the events that followed the initiation of this inquiry, see the Preliminary Decision Memorandum.6 A list of topics included in the Preliminary Decision Memorandum is included at the Appendix to this notice. The Preliminary Decision Memorandum is on file electronically via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at https://access.trade.gov, and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete public version of the Preliminary Decision Memorandum can be accessed directly at http://enforcement.trade.gov/frn/. The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The products covered by the Order are wire rod of approximately round cross section, 5.00 mm or more, but less than 19.00 mm, in solid cross-sectional diameter. For a complete description of the scope of the Order, see the Preliminary Decision Memorandum.

Scope of the Anti-Circumvention Inquiry

The products covered by this inquiry are wire rod with an actual diameter less than 4.75 mm and that are produced and/or exported to the United States by Deacero.

Methodology

Commerce is conducting this anti-circumvention inquiry in accordance with section 781(c) of the Act. For a full description of the methodology underlying Commerce’s preliminary determination, see the Preliminary Decision Memorandum.

Preliminary Determination

As detailed in the Preliminary Decision Memorandum, we preliminarily determine, pursuant to section 781(c) of the Act, that wire rod with an actual diameter less than 4.75 mm produced and/or exported by Deacero, constitutes merchandise “altered in form or appearance in minor respects” that should be considered subject to the Order. Therefore, we preliminarily determine that it is appropriate to include this merchandise within the class or kind of merchandise subject to the Order and to instruct U.S. Customs and Border Protection (CBP) to suspend any entries of wire rod with an actual diameter less than 4.75 mm produced and/or exported by Deacero.

Suspension of Liquidation

As stated above, Commerce has made a preliminary affirmative finding of circumvention of the Order with respect to wire rod with an actual diameter less than 4.75 mm produced and/or exported by Deacero. In accordance with section 19 CFR 351.225(i)(2), Commerce will direct CBP to suspend liquidation of entries of wire rod with an actual diameter less than 4.75 mm produced and/or exported by Deacero that were entered, or withdrawn from warehouse, for consumption on or after February 7, 2018, the date of initiation of the anti-circumvention inquiry. Pursuant to 19 CFR 351.225(i)(2), we will also instruct CBP to require a cash deposit of estimated duties equal to 12.56 percent ad valorem for each unliquidated entry of wire rod with an actual diameter less than 4.75 mm produced and/or exported by Deacero that was entered, or withdrawn from warehouse, for consumption on or after February 7, 2018.7 The suspension of liquidation instructions will remain in effect until further notice.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 21 days after the publication of this preliminary determination in the Federal Register, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.8 Pursuant to 19 CFR 351.300(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this anti-circumvention inquiry are encouraged

---

1 See Notice of Initiation of Antidumping Duty Investigations: Carbon and Certain Alloy Steel Wire Rod from Brazil, Canada, Egypt, Germany, Indonesia, Mexico, Moldova, South Africa, Trinidad and Tobago, Ukraine, and Venezuela, 66 FR 50164 (October 2, 2001).

2 See Notice of Antidumping Duty Orders: Carbon and Certain Alloy Steel Wire Rod from Brazil, Indonesia, Mexico, Moldova, Trinidad and Tobago, and Ukraine, 67 FR 65945 (October 29, 2002) (Order).

3 See Carbon and Certain Alloy Steel Wire Rod from Mexico: Affirmative Final Determination of Circumvention of the Antidumping Duty Order, 77 FR 59892 (October 1, 2012) (Final Circumvention Determination) and accompanying Issues and Decision Memorandum; see also Deacero S.A. de C.V. v. United States, 817 F.3d 1332 (Fed. Cir. 2016) (affirming the Final Circumvention Determination).


6 See Affirmative Preliminary Decision Memorandum of Circumvention Concerning Carbon and Certain Alloy Steel Wire Rod from Mexico, dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).


8 See 19 CFR 351.300; see also 19 CFR 351.303 (for general filing requirements).
to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 21 days after the date of publication of this notice. Requests should contain the party’s name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Notification to Interested Parties

This determination is issued and published in accordance with sections 781(c) of the Act and 19 CFR 351.225(f).


Christian Marsh,
Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Statutory and Regulatory Framework
V. Prior Anti-Circumvention Determination
VI. Parameters of the Anti-Circumvention Inquiry
VII. Arguments from Interested Parties
VIII. Analysis
IX. Recommendation

DEPARTMENT OF COMMERCE

International Trade Administration

Subsidy Programs Provided by Countries Exporting Softwood Lumber and Softwood Lumber Products to the United States; Request for Comment

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) seeks public comment on any subsidies, including stumpage subsidies, provided by certain countries exporting softwood lumber or softwood lumber products to the United States during the period January 1, 2018, through June 30, 2018.

DATES: Comments must be submitted within 30 days after publication of this notice.

ADDRESSES: See the Submission of Comments section below.

FOR FURTHER INFORMATION CONTACT: Kristen Johnson or Eric B. Greynolds, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4793 or (202) 482–6071, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 18, 2008, section 805 of Title VIII of the Tariff Act of 1930 (the Softwood Lumber Act of 2008) was enacted into law. Under this provision, the Secretary of Commerce is mandated to submit to the appropriate Congressional committees a report every 180 days on any subsidy provided by countries exporting softwood lumber or softwood lumber products to the United States, including stumpage subsidies.

Commerce submitted its last subsidy report on June 20, 2018. As part of its newest report, Commerce intends to include a list of subsidy programs identified with sufficient clarity by the public in response to this notice.

Request for Comments

Given the large number of countries that export softwood lumber and softwood lumber products to the United States, we are soliciting public comment only on subsidies provided by countries whose exports accounted for at least one percent of total U.S. imports of softwood lumber by quantity, as classified under Harmonized Tariff Schedule code 4407.1001 (which accounts for the vast majority of imports), during the period January 1, 2018, through June 30, 2018.

Official U.S. import data published by the United States International Trade Commission’s Tariff and Trade DataWeb indicate that four countries (Brazil, Canada, Germany, and Sweden) exported softwood lumber to the United States during that time period in amounts sufficient to account for at least one percent of U.S. imports of softwood lumber products. We intend to rely on similar previous six-month periods to identify the countries subject to future reports on softwood lumber subsidies. For example, we will rely on U.S. imports of softwood lumber and softwood lumber products during the period July 1, 2018, through December 31, 2018, to select the countries subject to the next report.

Under U.S. trade law, a subsidy exists where an authority: (i) Provides a financial contribution; (ii) provides any form of income or price support within the meaning of Article XVI of the GATT 1994; or (iii) makes a payment to a funding mechanism to provide a financial contribution to a person, or entrusts or directs a private entity to make a financial contribution, if providing the contribution would normally be vested in the government and the practice does not differ in substance from practices normally followed by governments, and a benefit is thereby conferred.1

Parties should include in their comments: (1) The country which provided the subsidy; (2) the name of the subsidy program; (3) a brief description (no more than 3–4 sentences) of the subsidy program; and (4) the government body or authority that provided the subsidy.

Submission of Comments

As specified above, to be assured of consideration, comments must be received no later than 30 days after the publication of this notice in the Federal Register. All comments must be submitted through the Federal eRulemaking Portal at http://www.regulations.gov, Docket No. ITA–2018–0002, unless the commenter does not have access to the internet. The materials in the docket will not be edited to remove identifying or contact information, and Commerce cautions against including any information in an electronic submission that the submitter does not want publicly disclosed. Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF formats only.

Commenters who do not have access to the internet may submit the original and one electronic copy of each set of comments by mail or hand delivery/courier.

All comments should be addressed to Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, at U.S. Department of Commerce, Room 18022, 1401 Constitution Avenue NW, Washington, DC 20230.

1 See section 771(5)(B) of the Tariff Act of 1930, as amended.
DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration


AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Notice of availability of Errata Document for the final environmental impact report/environmental impact statement.

SUMMARY: Notice is hereby given that the National Oceanic and Atmospheric Administration (NOAA) has published an errata document for the Final Environmental Impact Report/Environmental Impact Statement (FEIR/EIS) for permitting a desalination facility project (Project) in Monterey County, California. A notice of availability document (NOA) for the final EIR/EIS was published in the Federal Register on March 30, 2018 (83 FR 13737).

DATES: This notice is applicable October 19, 2018.


FOR FURTHER INFORMATION CONTACT: Karen Grimmer at 99 Pacific Ave., Bldg. 455A, Monterey, CA 93940, or call 831–647–4253, or email: montereybay@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

NOAA, as the Federal lead agency for purposes of the National Environmental Policy Act (NEPA), and the California Public Utilities Commission (CPUC), the state lead agency for purposes of the California Environmental Quality Act (CEQA), previously released a joint final environmental impact review/environmental impact statement (EIR/EIS) that analyzes the potential effects on the physical and human environment of the proposed Monterey Peninsula Water Supply Project.

II. Errata Document

The purpose of this notice is to inform the public that the errata document for the Final Environmental Impact Report/Environmental Impact Statement (FEIR/EIS) for the project is available for public inspection. It is available electronically on the website listed in the ADDRESSES section of this notice. It is also available by email by writing to the addresses identified in the FOR FURTHER INFORMATION CONTACT section of this notice.


Dated: September 13, 2018.

John Armor, Director for the Office of National Marine Sanctuaries.

Federal Register / Vol. 83, No. 203 / Friday, October 19, 2018 / Notices 53033
maritime mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization may be provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses referred to in shorthand as "mitigation and requirements pertaining to the mitigation, monitoring and reporting of such take"


National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 et seq.) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (i.e., the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment. This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental harassment authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On July 26, 2018, NMFS received a request from WSDOT for an IHA to take marine mammals incidental to US 101/ Chehalis River Bridge-Scour Repair in the State of Washington. The application was deemed adequate and complete on September 21, 2018. WSDOT’s request is for take of small numbers of harbor seal (Phoca vitulina); California sea lion (Zalophus californianus); Steller sea lion (Eumetopias jubatus); gray whale (Eschrichtius robustus); and harbor porpoise (Phocoena phocoena) by Level B harassment only. Neither WSDOT nor NMFS expects serious injury or mortality to result from this activity and, therefore, an IHA is appropriate. NMFS previously issued an IHA to WSDOT to incidentally take five species of marine mammal by Level B harassment. The IHA was issued on October 10, 2017 (82 FR 50628; November 1, 2017) and is valid from July 1, 2018 through June 30, 2019. However, WSDOT has made minor changes to the project plan and delayed the work by one year. Therefore, WSDOT has requested that NOAA Fisheries re-issue the IHA with the dates changed to accommodate the analyzed work with minor modifications to the number of piles driven and removed as well as the number of animals authorized for take. No work was conducted under the original IHA.

Description of the Proposed Activity

Overview

The proposed IHA would authorize work for the US 101/Chehalis River Bridge-Scour Repair Project in Washington State between July 15, 2018 and February 15, 2020. Vibratory pile driving will be required to remove and install timber piles, steel sheets and steel H-piles. Sound in the water from vibratory driving may result in behavioral harassment. NMFS previously issued an IHA to WSDOT to incidentally take five species of marine mammal by Level B harassment on October 18, 2017 (82 FR 50628; November 1, 2017). That IHA is valid from July 1, 2018 through June 30, 2019. However, WSDOT has made minor changes to the project plan and delayed the work by one year. Therefore, WSDOT has requested that NMFS re-issue the IHA with the dates changed to accommodate the analyzed work with minor modifications to the number of piles driven and removed as well as the number of animals authorized for take. No work was conducted under the original IHA. The purpose of the US 101/Chehalis River Bridge-Scour Repair Project is to make the bridge foundation stable and protect the foundation from further scour. Bridge scour is the removal of sediment such as sand and gravel from around bridge abutments or piles. Scour, caused by swiftly moving water, can scoop out scour holes, compromising the integrity of a structure. WSDOT plans to remove debris from the scour area, fill the scour void under Pier 14 with cement (to protect the pilings from marine borers), fill the scour hole, and protect the pier with scour resistant material.

Note that WSDOT has made revisions to the number and types of piles that would be installed and removed under the proposed 2019 IHA. The first change is the removal of 44 timber piles (some of which may be treated with creosote) from the immediate vicinity of the scour repair project. Additionally, 18 sheet piles will be temporarily installed adjacent to Pier 14, instead of the 44 sheet piles originally proposed.

Dates and Duration

Due to NMFS and the U.S. Fish and Wildlife Service (USFWS) in-water work timing restrictions to protect Endangered Species Act (ESA)-listed salmonids, planned WSDOT in-water construction is limited each year to July 15 through February 15. For this project, in-water construction is planned to take place between July 15, 2019 and September 30, 2019. The proposed IHA would be effective from July 15, 2019 to February 15, 2020. The estimated maximum time period for pile installation and removal is 37 hours over 6 days (Table 1).

Specific Geographic Region

The US 101/Chehalis River Bridge is located in the City of Aberdeen, Grays Harbor County, Washington (Figure 1–2 in the IHA application). Grays Harbor is an estuarine bay located 45 miles (72 km) north of the mouth of the Columbia River, on the Southwest Pacific coast of Washington state. The bridge is located in Township 17 North, Range 9 West, Section 9, where the Chehalis River enters Grays Harbor. Land use in the Aberdeen area is a mix of residential, commercial, industrial, and open space and/or undeveloped lands (Figure 1–2 in the IHA application).

Detailed Description of Specific Activity

Vibratory hammers are commonly used in steel pile driving and removal when appropriate sediments are found at a specific project site. A pile is...
typical placement into position using a vibratory hammer. If necessary, some deteriorated piles may require cutting below the ground level to minimize turbidity. If use of a clamshell bucket is required due to pile breakage, turbidity curtains will be employed.

A steel template will be located adjacent to or attached to Pier 14. The template will likely be constructed using six steel H piles which will be installed using a vibratory hammer. Using the template as a guide, 18 sheet piles will be driven with a vibratory hammer into the substrate to form a temporary interlocked sheet pile wall shoring system around the scour repair area (Table 1). After the sheet piles have been installed, the template will be removed.

Table 1—Pile Removal Mitigation and Scour Repair Pile Summary

<table>
<thead>
<tr>
<th>Method</th>
<th>Pile type</th>
<th>Number of piles</th>
<th>Minutes per pile</th>
<th>Total minutes</th>
<th>Duration (hours)</th>
<th>Piles per day</th>
<th>Duration (11-hour work days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vibratory Removal</td>
<td>14-inch diameter timber</td>
<td>44</td>
<td>30</td>
<td>1,320</td>
<td>22</td>
<td>22</td>
<td>2</td>
</tr>
<tr>
<td>Vibratory Driving</td>
<td>Sheet</td>
<td>18</td>
<td>30</td>
<td>540</td>
<td>9</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Vibratory Driving</td>
<td>H pile</td>
<td>6</td>
<td>30</td>
<td>180</td>
<td>3</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Vibratory Removal</td>
<td>H pile</td>
<td>6</td>
<td>30</td>
<td>180</td>
<td>3</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td>2,220</td>
<td>37</td>
<td></td>
<td>6.0</td>
</tr>
</tbody>
</table>

Once the shoring system is in place, cementitious material will be tremie pumped underwater inside the shoring system to fill the voids between the riverbed and the pier seal. A tremie is a large metal hopper and pipe used to distribute freshly mixed concrete over an underwater site. The foot of the pipe is kept below the concrete level, while the upper level of the concrete in the pipe is kept above the water level to prevent the water diluting the concrete. The concrete falls by gravity and is continuously placed until the shaft is full. This material will protect the untreated wood pier piling from marine borers. Following installation of the cementitious sealing material, the shoring system will be considered a permanent feature of the scour repair. The sheet piles will be cut off and removed to the level of final concrete placement. The final steps will be the placement of scour resistant material, such as rip rap, on and around the pier and in the scour hole to protect the pier from future erosion. The cutting of sheet piles and placement of rip rap is not anticipated to result in take.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (please see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected species. Additional information regarding population trends and threats may be found in NMFS’s Stock Assessment Reports (https://www.fisheries.noaa.gov/national/marine-mammal-protection/stock-assessments) and more general information about these species (e.g., physical and behavioral descriptions) may be found on NMFS’s website (https://www.fisheries.noaa.gov/find-species).

Table 2 lists all species with expected potential for occurrence in the project area and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2017). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS’s SARs). While no mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS’s stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS’s U.S. 2017 SARs (https://www.fisheries.noaa.gov/national/marine-mammal-protection/stock-assessments) and draft U.S. 2018 SARs (https://www.fisheries.noaa.gov/national/marine-mammal-protection/draft-stock-assessment-reports). All values presented in Table 2 are the most recent available at the time of publication.
All species that could potentially occur in the proposed survey areas are included in Table 2.

**Harbor Seals**

Harbor seals haul out on rocks, reefs and beaches, and feed in marine, estuarine and occasionally fresh waters. Harbor seals display strong fidelity for haul out sites (Pitcher and Calcants 1979; Pitcher and McAllister 1981). Harbor seals in Grays Harbor are part of the Oregon/Washington Coast Stock. In Grays Harbor, pups are born from mid-April through July (WDFW 2012). Of the pinniped species that commonly occur within the region of activity, harbor seals are the most common and the only pinniped that breeds and remains in the inland marine waters of Washington year-round (Calambokidis and Baird 1994). Harbor seals are non-migratory; their local movements are associated with such factors as tides, weather, season, food availability and reproduction (Scheffer and Slipp 1944; Fisher 1952; Bigg 1969, 1981). They are not known to make extensive pelagic migrations, although some long-distance movements of tagged animals in Alaska (108 miles) and along the U.S. west coast (up to 342 miles) have been recorded (Pitcher and McAllister 1981).

In order to estimate abundance, aerial surveys of harbor seals in Oregon and Washington were conducted by the National Marine Mammal Laboratory (NMML) and the Oregon and Washington Departments of Fish and Wildlife (ODFW and WDFW) during the 1999 pupping season. Total numbers of hauled-out seals (including pups) were counted during these surveys. In 1999, the mean count of harbor seals occurring along the Washington coast was 10,430 (CV = 0.14) animals. In 1999, the mean count of harbor seals occurring along the Oregon coast and in the Columbia River was 5,735 (CV = 0.14) animals. Combining these counts results in 16,165 (CV = 0.10) harbor seals in the Oregon/Washington Coast stock. However, because the most recent abundance estimate is >8 years old, there is no current estimate of abundance available for this stock and the current population trend is unknown.

The nearest documented harbor seal haul out site to the US 101/Chehalis River Bridge is a low-tide haul out located seven miles to the west. According to Jeffries, *et al.* (2000), all haul outs in Grays Harbor are associated with tidal flats; at high tide it is assumed that these animals are foraging elsewhere in the estuary.

**California Sea Lion**

California sea lions are found along the west coast from the southern tip of Baja California to southeast Alaska. They breed mainly on offshore islands from Southern California’s Channel Islands to Alaska’s Pribilof Island.
Islands south to Mexico. Non-breeding males often roam north in spring foraging for food (Everitt et al. 1980).

Since the mid-1980s, increasing numbers of California sea lions have been documented feeding on fish along the Washington coast and, more recently, in the Columbia River as far upstream as Bonneville Dam, 145 mi (233 km) from the river mouth. All age classes of males are seasonally present in Washington waters (Jeffries, et al. 2000). California sea lions do not avoid areas with heavy or frequent human activity, but rather may approach certain areas to investigate. This species typically does not flush from a buoy or haul out if approached. The nearest documented California sea lion haul out sites to the U.S. 101 Chehalis River Bridge project site are at Split Rock, 35 miles north of the entrance to Grays Harbor; and at the mouth of the Columbia River, 46 miles south of the entrance to Grays Harbor (Jeffries, et al. 2000). A few California sea lions may haul out on docks and buoys in the vicinity of the Westport marina, located 15 miles west of the project site.

**Steller Sea Lion**

The Steller sea lion is a pinniped and the largest of the eared seals. Steller sea lion populations that primarily occur east of 144° W (Cape Suckling, Alaska) comprise the Eastern Distinct Population Segment (DPS), which was de-listed and removed from the Endangered Species List on November 4, 2013 (78 FR 66140). This stock is referred to as the “Pacific Coast Feeding Group” (NMFS 2015a).

Gray whales are known to use Grays Harbor. For example, during a 1996 survey 27 different whales were recorded in the Harbor. (Calambokidis and Guan 1997). However, between 1998 and 2010, gray whale numbers peaked in the spring followed by slightly lesser numbers in the fall in a study area that included Grays Harbor and coastal waters along the south Washington coast. Note, that much of the in-water pile driving work for the proposed action is likely to occur during summer months. (Calambokidis, et al. 2012)

**Harbor Porpoise**

The harbor porpoise inhabits temporal, subarctic, and arctic waters. Harbor porpoise are known to occur year-round in the Oregon/ Washington coastal waters (Jeffries, et al., 2000). California sea lions may haul out on docks and buoys in the vicinity of the Westport marina, located 15 miles west of the project site.

**Gray Whale**

During summer and fall, most whales in the Eastern North Pacific population feed in the Chukchi, Beaufort and northwestern Bering Seas. An exception to this is the relatively small number of whales (approximately 200) that summer and feed along the Pacific coast between Kodiak Island, Alaska and northern California (Calambokidis et al. 2012), referred to as the “Pacific Coast Feeding Group” (NMFS 2015a).

Gray whales are known to use Grays Harbor. For example, during a 1996 survey 27 different whales were recorded in the Harbor. (Calambokidis and Guan 1997). However, between 1998 and 2010, gray whale numbers peaked in the spring followed by slightly lesser numbers in the fall in a study area that included Grays Harbor and coastal waters along the south Washington coast. Note, that much of the in-water pile driving work for the proposed action is likely to occur during summer months. (Calambokidis, et al. 2012)

**HARBOR PORPOISE**

- The harbor porpoise inhabits temporal, subarctic, and arctic waters.
- Harbor porpoise are known to occur year-round in the Oregon/Washington coastal waters (Jeffries, et al., 2000).
- California sea lions may haul out on docks and buoys in the vicinity of the Westport marina, located 15 miles west of the project site.

**GRAY WHALE**

- During summer and fall, most whales in the Eastern North Pacific population feed in the Chukchi, Beaufort and northwestern Bering Seas. An exception to this is the relatively small number of whales (approximately 200) that summer and feed along the Pacific coast between Kodiak Island, Alaska and northern California (Calambokidis et al. 2012), referred to as the “Pacific Coast Feeding Group” (NMFS 2015a).
- Gray whales are known to use Grays Harbor. For example, during a 1996 survey 27 different whales were recorded in the Harbor. (Calambokidis and Guan 1997). However, between 1998 and 2010, gray whale numbers peaked in the spring followed by slightly lesser numbers in the fall in a study area that included Grays Harbor and coastal waters along the south Washington coast. Note, that much of the in-water pile driving work for the proposed action is likely to occur during summer months. (Calambokidis, et al. 2012)
Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section includes a summary and discussion of the ways that components of the specified activity may impact marine mammals and their habitat. The Estimated Take by Incidental Harassment section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take by Incidental Harassment section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and how those impacts on individuals are likely to impact marine mammal species or stocks.

The proposed River Bridge-Scour repair project will utilize in-water vibratory pile driving and pile removal that could adversely affect marine mammal species and stocks by exposing them to elevated noise levels in the vicinity of the activity area.

Exposure to high intensity sound for a sufficient duration may result in auditory effects such as a noise-induced threshold shift (TS)—an increase in the auditory threshold after exposure to noise (Finneran et al. 2005). Factors that influence the amount of threshold shift include the amplitude, duration, frequency content, temporal pattern, and energy distribution of noise exposure. The magnitude of hearing threshold shift normally decreases over time following cessation of the noise exposure. The amount of threshold shift just after exposure is the initial threshold shift. If the threshold shift eventually returns to zero (i.e., the threshold returns to the pre-exposure value), it is a temporary threshold shift (Southall et al. 2007).

Temporary Threshold Shift (noise-induced loss of hearing)—When animals exhibit reduced hearing sensitivity (i.e., sounds must be louder for an animal to detect them) following exposure to an intense sound or sound for long duration, it is referred to as TS. An animal can experience temporary threshold shift (TTS) or permanent threshold shift (PTS). TTS can last from minutes to hours to days (i.e., there is complete recovery), can occur in specific frequency ranges (i.e., an animal might only have a temporary loss of hearing sensitivity between the frequencies of 1 and 10 kHz), and can be of varying amounts (for example, an animal's hearing sensitivity might be reduced initially by only 6 dB or reduced by 30 dB). PTS is permanent, but some recovery is possible. PTS can also occur in a specific frequency range and amount as mentioned above for TTS.

For marine mammals, published data are limited to the captive bottlenose dolphin, beluga, harbor porpoise, and Yangtze finless porpoise (Finneran et al. 2002, 2003, 2005, 2007, 2010a, 2010b; Finneran and Schlundt, 2010; Lucke et al. 2009; Popov et al. 2011a, 2011b; Kastelein et al., 2012a; Schlundt et al., 2000; Nachtigall et al., 2003, 2004). For pinnipeds in water, data are limited to measurements of TTS in harbor seals, an elephant seal, and California sea lions (Kastak et al., 1999, 2005; Kastelein et al., 2012b).

Lucke et al. (2009) found a TS of a harbor porpoise after exposing it to airgun noise with a received SPL at 200.2 dB (peak-to-peak) re: 1 µPa, which corresponds to a sound exposure level (SEL) of 164.5 dB re: 1 µPa2 s after integrating exposure. Because the airgun noise is a broadband impulse, one cannot directly determine the equivalent of rms SPL from the reported peak-to-peak SPLs. However, applying a conservative conversion factor of 16 dB for broadband signals from seismic surveys (McCaulley et al. 2000) to correct for the difference between peak-to-peak levels reported in Lucke et al. (2009) and rms SPLs, the rms SPL for TTS would be approximately 184 dB re: 1 µPa, and the received levels associated with PTS would be higher. However, NMFS recognizes that TTS of harbor porpoises is lower than other cetacean species empirically tested (Finneran and Schlundt 2010; Finneran et al. 2002; Kastelein and Jennings 2012).

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold dB), duration (covering time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that occurs during a time where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. Also, depending on the degree and frequency range, the effects of PTS on an animal could range in severity, although it is considered generally more serious because it is a permanent condition. Of note, reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall et al. 2007), so one can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Masking—In addition, chronic exposure to excessive, though not high-intensity, noise could cause masking at particular frequencies for marine mammals that utilize sound for vital biological functions (Clark et al. 2009). Acoustic masking is when other noises such as from human sources interfere with animal detection of acoustic signals such as communication calls, echolocation sounds, and environmental sounds important to marine mammals. Therefore, under certain circumstances, marine mammals whose acoustical sensors or environment are being severely masked could also be impaired from maximizing their performance fitness in survival and reproduction.

Masking occurs at the frequency band that the animals utilize. Therefore, since noise generated from vibratory pile driving activity is mostly concentrated at low frequency ranges, it may have less effect on high-frequency echolocation sounds by odontocetes (toothed whales). However, lower frequency man-made noises are more likely to affect detection of communication calls and other potentially important natural sounds such as surf and prey noise. It may also affect communication signals when they occur near the noise band and thus reduce the communication space of animals (e.g., Clark et al. 2009) and cause increased stress levels (e.g., Foote et al. 2004; Holt and Noren 2009).

Unlike TS, masking, which can occur over large temporal and spatial scales, can potentially affect the species at
population, community, or even ecosystem levels, as well as individual levels. Masking affects both senders and receivers of the signals and could have long-term chronic effects on marine mammal species and populations. Recent science suggests that low frequency ambient sound levels have increased by as much as 20 dB (more than three times in terms of sound pressure level) in the world’s ocean from pre-industrial periods, and most of these increases are from distant shipping (Hildebrand 2009).

Acoustic Effects, Airborne—

Pinnipeds that occur near the project site could be exposed to airborne sounds associated with pile driving that have the potential to cause behavioral harassment, depending on their distance from pile driving activities. Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA.

Airborne noise will primarily be an issue for pinnipeds that are swimming or hauled out near the project site within the range of noise levels elevated above the acoustic criteria. We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause hauled-out pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to temporarily abandon the area and move further from the source. However, these animals would previously have been ‘taken’ because of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Behavioral disturbance—Finally, marine mammals’ exposure to certain sounds could lead to behavioral disturbance (Richardson et al., 1995), such as: changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where noise sources are located; and/or flight responses (e.g., pinnipeds flushing into water from haulouts or rookeries).

The onset of behavioral disturbance from anthropogenic noise depends on both external factors (characteristics of noise sources and their paths) and the receiving animals (hearing, motivation, experience, demography) and is also difficult to predict (Southall et al., 2007). Currently NMFS uses a received level of 160 dB re 1 μPa (rms) to predict the onset of behavioral harassment from impulse noises (such as impact pile driving), and 120 dB re 1 μPa (rms) for continuous noises (such as vibratory pile driving). For the proposed project, only 120 dB re 1 μPa (rms) is considered for effects analysis because only vibratory pile driving and removal will be employed.

The biological significance of many of these behavioral disturbances is difficult to predict especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be biologically significant if the change affects growth, survival, and/or reproduction, which depends on the severity, duration, and context of the effects.

Habitat—The primary potential impacts to marine mammal habitat are associated with elevated sound levels produced by pile driving and removal associated with marine mammal prey species. However, other potential impacts to the surrounding habitat from physical disturbance are also possible. Prey species for the various marine mammals include marine invertebrates and fish species. Short-term effects would occur to marine invertebrates during removal of existing piles. This effect is expected to be minor and short-term on the overall population of marine invertebrates in Grays Harbor. Construction will also have temporary effects on salmonids and other fish species in the project area due to disturbance, turbidity, noise, and the potential resuspension of contaminants. All in-water work will occur during the designated in-water work window, to minimize effects on juvenile salmonids.

SPLs from vibratory driving generally do not have the potential to injure or kill fish in the immediate area. Experiments have shown that fish can sense both the strength and direction of sound (Hawkins and Horner 1981). Primary factors determining whether a fish can sense a sound signal, and the potential direct frequency of the signal and the strength of the signal in relation to the natural background noise level. The level of sound at which a fish will react or alter its behavior is usually well above the detection level. Fish have been found to react to sounds when the sound level increased to about 20 dB above the detection level of 120 dB; however, the response threshold can depend on the time of year and the fish’s physiological condition (Engas et al. 1993). Any disturbance to fish species would be short-term and fish would return to their pre-disturbance behavior once the pile driving activity ceases. The proposed construction would have little, if any, impact on the abilities of marine mammals to feed in the area where construction work is proposed.

There are no critical habitats or other biologically important areas near the proposed project location, although biologically important feeding and migration areas for gray whales have been established along the coast beyond the mouth of Grays Harbor. However, the project site is upriver to the east of the harbor, so there will be no impacts to these areas. While harbor seals, California sea lions, and other marine mammals may be present, the area is not an established rookery or breeding ground for local populations. Additionally, during construction activity only a small fraction of the available habitat would be ensonified.

Short-term turbidity is a water quality effect of most in-water work, including pile driving. Cetaceans are not expected to be close enough to the Chehalis River Bridge to experience turbidity, and any pinnipeds will be transiting the terminal area and could avoid localized areas of turbidity. Therefore, the impact from increased turbidity levels is expected to be discountable to marine mammals. For these reasons, any adverse effects to marine mammal habitat in the area from WSDOT’s proposed project would be minor.

Estimated Take

This section provides an estimate of the number of incidental takes proposed for authorization through this IHA, which will inform both NMFS’ consideration of “small numbers” and the negligible impact determination. Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines “harassment” as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral
Authorized takes would be by Level B harassment only, in the form of disruption of behavioral patterns for individual marine mammals resulting from exposure to vibratory driving. Based on the nature of the activity and the anticipated effectiveness of the mitigation measures (i.e., shutdown, establishment and monitoring of harassment zones) discussed in detail below in Proposed Mitigation section), Level A harassment is neither anticipated nor proposed to be authorized.

As described previously, no mortality is anticipated or proposed to be authorized for this activity. Below we describe how the take is estimated.

Generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be sonified above these levels in a day; (3) the density or occurrence of marine mammals within these sonified areas; and, (4) the number of days of activities. We note that while these basic factors can contribute to a basic calculation to provide an initial prediction of takes, additional information that can qualitatively inform take estimates is also sometimes available (e.g., previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimate.

## Acoustic Thresholds

Using the best available science, NMFS has developed acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment for non-explosive sources—NMFS’ Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0) (NMFS, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). WSDOT's proposed activity includes the use non-impulsive (vibratory driving) sources.

These thresholds are provided in Table 3 below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2018 Technical Guidance, which may be accessed at: https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.

### Table 3—Thresholds Identifying the Onset of Permanent Threshold Shift

<table>
<thead>
<tr>
<th>Hearing group</th>
<th>Impulsive</th>
<th>Non-impulsive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(received level)</td>
<td></td>
</tr>
<tr>
<td>Low-Frequency (LF) Cetaceans</td>
<td>$L_{E,LF,24h} = 183 \text{ dB}$</td>
<td>$L_{E,LF,24h} = 199 \text{ dB}$</td>
</tr>
<tr>
<td>Mid-Frequency (MF) Cetaceans</td>
<td>$L_{E,MF,24h} = 185 \text{ dB}$</td>
<td>$L_{E,MF,24h} = 198 \text{ dB}$</td>
</tr>
<tr>
<td>High-Frequency (HF) Cetaceans</td>
<td>$L_{E,HF,24h} = 155 \text{ dB}$</td>
<td>$L_{E,HF,24h} = 173 \text{ dB}$</td>
</tr>
<tr>
<td>Phocid Pinnipeds (PW) (Underwater)</td>
<td>$L_{E,PW,24h} = 185 \text{ dB}$</td>
<td>$L_{E,PW,24h} = 201 \text{ dB}$</td>
</tr>
<tr>
<td>Otarid Pinnipeds (OW) (Underwater)</td>
<td>$L_{E,OW,24h} = 203 \text{ dB}$</td>
<td>$L_{E,OW,24h} = 219 \text{ dB}$</td>
</tr>
</tbody>
</table>

*Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

**Note:** Peak sound pressure ($L_{pk}$) has a reference value of 1 ìPa, and cumulative sound exposure level ($L_{E}$) has a reference value of 1µPa·s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript “flat” is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (i.e., varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.
Ensonified Area

Here, we describe operational and environmental parameters of the activity that will feed into identifying the area ensonified above the acoustic thresholds, which include source levels and transmission loss coefficient.

Reference sound source levels used by WSDOT for vibratory driving and removal activities were derived from several sources. WSDOT utilized in-water measurements generated by the Greenbusch Group (2018) from the WDOT Seattle Pier 62 project (83 FR 39709) to establish proxy sound source levels for vibratory removal of 14-inch timber piles. The results determined unweighted rms ranging from 140 dB to 169 dB. WSDOT used the 75th percentile of these values (161 dB rms measured at 10 meters) as a proxy for vibratory removal of 14-inch timber piles at the Chehalis River Bridge. However, NMFS reviewed the report by the Greenbusch Group (2018) and determined that the findings were derived by pooling together all steel pile and timber pile at various distance measurements data together. The data was not normalized to the standard 10 m distance. NMFS analyzed source measurements at different distances for all 63 individual timber piles that were removed and normalized the values to 10 m. The results showed that the median is 152 dB SPL rms. This value was used as the source level for vibratory removal of 14-inch timber piles.

The proposed project includes vibratory driving of 18 sheet piles as well as vibratory driving and removal of six steel H piles. Based on in-water measurements at the Elliot Bay Seawall Project, vibratory pile driving of steel sheet piles generated a source level of 165 dB rms measured at 10 m (Greenbusch Group 2015). According to CalTrans (2015), 150 dB rms at 10 m is a typical source level for vibratory driving and removal of steel H piles.

Level B Harassment Zones

The practical spreading model was used by WSDOT to establish the Level B harassment zones for all vibratory pile installation and removal activities. Practical spreading is described in full detail below.

Pile driving generates underwater noise that can potentially result in disturbance to marine mammals in the project area. Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

\[ TL = B \times \log_{10} (R1/R2), \]

Where:
\[ R1 = \text{the distance of the modeled SPL from the driven pile, and} \]
\[ R2 = \text{the distance from the driven pile of the initial measurement.} \]

Utilizing the practical spreading loss model, WSDOT determined the distance and area where the noise will fall below the behavioral effects threshold of 120 dB rms. The distances and areas are shown in Table 4. Note that the ensonified area is based on a GIS analysis of the area accounting for structures and landmasses which would block underwater sound transmission.

<table>
<thead>
<tr>
<th>Pile type</th>
<th>Level B harassment zone isopleth (meters)</th>
<th>Area (km²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14-inch timber vibratory removal</td>
<td>1,359</td>
<td>0.93</td>
</tr>
<tr>
<td>Steel sheet vibratory driving</td>
<td>10,000</td>
<td>2.04</td>
</tr>
<tr>
<td>Steel H-pile vibratory driving and removal</td>
<td>1,000</td>
<td>0.67</td>
</tr>
</tbody>
</table>

Level A Harassment Zones

When the NMFS Technical Guidance (2016) was published, in recognition of the fact that ensonified area/volume could be more technically challenging to predict because of the duration component in the new thresholds, we developed a User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to help predict takes. We note that because of some of the assumptions included in the methods used for these tools, we anticipate that isopleths produced are typically going to be overestimates of some degree. However, these tools offer the best way to predict appropriate isopleths when more sophisticated 3D modeling methods are not available, and NMFS continues to develop ways to quantitatively refine these tools, and will qualitatively address the output where appropriate. For stationary sources such as vibratory driving, NMFS User Spreadsheet predicts the closest distance at which, if a marine mammal remained at that distance the whole duration of the activity, it would not incur PTS. User Spreadsheet inputs are shown in Table 5 and outputs are shown in Table 6. Note that since no Level A harassment take is proposed, the areas of Level A harassment zones were not calculated.
Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations. There is little abundance or density data available for marine mammal species that are likely to occur within Grays Harbor and which could potentially be found in the Chehalis River near the project site. In most cases, WSDOT relied on density data from the U.S. Navy Marine Species Density Database (NMSDD) (U.S. Navy 2015). NMFS concurs that this, and the exceptions described below, represent the best available data for use here.

Harbor Seal

While the NMSDD (U.S. Navy 2015) estimates the density of harbor seals in the waters offshore of Grays Harbor as 0.279 animals per square kilometer, WSDOT relied on a study which identified 44 harbor seal haul outs in Grays Harbor and provided very rough estimates of the number of seals at each site. Twenty-seven haul outs had less than 100 animals; 16 haul outs had 100–500 animals; and two haul outs were reported to support over 500 animals (Jeffries et al. 2000). These data likely represent the best estimate of harbor seal numbers in Grays Harbor. Using median numbers of each haul out estimate range resulted in an estimated 7,150 harbor seals in Grays Harbor. The area of the estuary during mean higher high water (243 km²) was used to derive a density estimate of 29.4 harbor seals per square kilometer.

California Sea Lion

Only 10 California sea lion strandings have been documented between 2006 and 2015 (NMFS 2016c), and no haul outs have been identified. Therefore, it is expected that the density of California sea lions in Grays Harbor is low. The NMSDD (U.S. Navy 2015) estimates the density of California sea lions in the waters offshore of Grays Harbor as ranging from 0.020 to 0.033 animals per square kilometer in summer and fall. The higher estimate is used as a surrogate for Grays Harbor.

Steller Sea Lion

According to the NMFS National Stranding Database, there were four confirmed Steller sea lion strandings in Grays Harbor between 2006 and 2015 (NMFS 2016c) and no haul outs have been identified in Grays Harbor. The NMSDD (U.S. Navy 2015) estimates the density of Steller sea lions in the waters offshore of Grays Harbor as 0.0145 animals per square kilometer. This estimate is used as a surrogate for Grays Harbor.

Gray Whale

Between 1998 and 2010, gray whale numbers peaked in spring and fall in a study area that included waters inside Grays Harbor and coastal waters along the south Washington coast (Calambokidis, et al. 2012). However, no density estimates are available for Grays Harbor. The NMSDD (U.S. Navy 2015) estimates the density of gray whales in nearshore waters near Grays Harbor as 0.00045 animal per square kilometer in summer and fall. This density is used for Grays Harbor.

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate. No Level A harassment take is likely because of the small injury zones and relatively low average animal density in the area. Since the largest Level A harassment distance is only 50.9 m from the source for high-frequency cetaceans (harbor porpoise), NMFS considers that WSDOT can effectively monitor such small zones to implement shutdown measures and avoid Level A harassment takes. Therefore, no Level A harassment take of marine mammal is proposed or authorized.
NMFS used an estimated harbor seal density of 29.4 animals/km² in the US 101/Chehalis River Bridge-Scour Repair Project area to estimate the following number of Level B harassment exposures that may occur:

- 14-inch timber pile removal: 29.4 animals/km² * 0.93 km² * 2 days = 54.68
- Sheet pile installation: 29.4 animals/km² * 2.04 km² * 2 days = 119.95
- H-pile installation and removal: 29.4 animals/km² * 0.67 km² * 2 days = 39.39

Based on the sum of the equations above, NMFS proposes to authorize 214 takes of harbor seals by Level B harassment.

NMFS inserted the California sea lion density of 0.033 animals/km² into the same equation used above for harbor seals to estimate Level B harassment exposures. Based on the sum of the equations, an estimated 0.24 California sea lions would be taken by Level B harassment. Due to this low value, NMFS conservatively proposes to authorize the take of two California sea lions each day of in-water activities, resulting in 12 takes by Level B harassment.

NMFS estimated take of Steller sea lions by inserting a density of 0.0145 animals/km² into the same equation used above for harbor seals resulting in 0.10 takes of sea lions. Given the low value, NMFS conservatively proposes to authorize the take of two Steller sea lions during each day of in-water activities, resulting in 12 takes by Level B harassment.

NMFS used the same equation that was used for harbor seals to estimate take for gray whales by inserting a density value of 0.00045 animals/km². Since this resulted in a value less than one, NMFS proposes to authorize Level B harassment take of two gray whales per day based on average group size.

A density value of 1.67 animal/km² for harbor porpoises was plugged into the harbor seal equation to arrive at an estimated 12.1 takes. Therefore, NMFS is proposing to authorize 12 harbor porpoise takes by Level B harassment.

Table 7 shows total number of authorized Level B harassment takes and take as a percentage of population for each of the species.

<table>
<thead>
<tr>
<th>Species</th>
<th>Proposed authorized take</th>
<th>% population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harbor seal</td>
<td>214</td>
<td>1.9</td>
</tr>
<tr>
<td>California sea lion</td>
<td>12</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Steller sea lion</td>
<td>12</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Gray whale</td>
<td>2</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Harbor porpoise</td>
<td>12</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Proposed Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

1. The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned) the likelihood of effective implementation (probability implemented as planned), and;

2. The practicability of the measures for applicant implementation, which may consider such things as cost, impact on operations, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Mitigation for Marine Mammals and Their Habitat

Temporal and Seasonal Restrictions—Timing restrictions would be used to avoid in-water work when ESA-listed salmonids are most likely to be present. The combined work window for in-water work for the U.S. 101/Chehalis River Bridge –Scour Project is July 15 through February 15. Furthermore, work may only occur during daylight hours, when visual monitoring of marine mammals can be effectively conducted.

Establishment of Shutdown Zone—For all pile driving activities, WSDOT will establish a shutdown zone. The purpose of a shutdown zone is generally to define an area within which shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). In this case, shutdown zones are intended to contain areas in which sound pressure levels (SPLs) equal or exceed acoustic injury criteria for authorized species. If a marine mammal is observed at or within the shutdown zone, work must shut down (stop work) until the individual has been observed outside of the zone, or has not been observed for at least 15 minutes for all marine mammals. A determination that the shutdown zone is clear must be made during a period of good visibility (i.e., the entire shutdown zone and surrounding waters must be visible to the naked eye). If a marine mammal approaches or enters the shutdown zone during activities or pre-activity monitoring, all pile driving and removal activities at that location must be halted or delayed, respectively. If pile driving or removal is halted or...
delayed due to the presence of a marine mammal, the activity may not resume or commence until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or 15 minutes have passed without re-detection of the animal. Pile driving and removal activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than thirty minutes. Shutdown zone sizes are shown in Table 8.

### Table 8—Shutdown Zones for Various Pile Driving Activities and Marine Mammal Hearing Groups (Meters)

<table>
<thead>
<tr>
<th>Source type</th>
<th>Low-frequency Cetaceans</th>
<th>High-frequency Cetaceans</th>
<th>Phocid pinnipeds</th>
<th>Otarid pinnipeds</th>
</tr>
</thead>
<tbody>
<tr>
<td>14-inch timber removal</td>
<td>10</td>
<td>15</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Sheet pile installation</td>
<td>35</td>
<td>50</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>H-pile installation and removal</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

For in-water heavy machinery activities other than pile driving, if a marine mammal comes within 10 m, operations must cease and vessels must reduce speed to the minimum level required to maintain steering and safe working conditions. WSDOT must also implement shutdown measures if the cumulative total number of individuals observed within the Level B harassment monitoring zones for any particular species reaches the number authorized under the IHA and if such marine mammals are sighted within the vicinity of the project area and are approaching the Level B Harassment/Monitoring Zone during in-water construction activities.

Establishment of Level B Harassment/Monitoring Zones—WSDOT must identify and establish Level B harassment zones which are areas where SPLs equal or exceed 120 dB rms. Observation of monitoring zones enables observers to be aware of and communicate the presence of marine mammals in the project area and outside the shutdown zone and thus prepare for potential shutdowns of activity. Monitoring zones are also used to document instances of Level B harassment. Monitoring zone isopleths are shown in Table 4.

### Pre-Activity Monitoring

Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, the observer shall observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone shall be cleared when a marine mammal has not been observed within the zone for that 30-minute period. When a marine mammal permitted for Level B harassment take is present in the Level B harassment zone, piling activities may begin and Level B harassment take shall be recorded. As stated above, if the entire Level B harassment zone is not visible at the start of construction, piling driving activities can begin. If work ceases for more than 30 minutes, the pre-activity monitoring of both the Level B harassment and shutdown zone shall commence.

Based on our evaluation of the applicant’s proposed measures, NMFS has preliminarily determined that the proposed mitigation measures provide the means effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

#### Proposed Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth, requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (e.g., presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (e.g., source characterization, propagation, ambient noise); (2) affected species (e.g., life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (e.g., age, calving or feeding areas);
  - Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
  - How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
  - Effects on marine mammal habitat (e.g., marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
  - Mitigation and monitoring effectiveness.

#### Proposed Monitoring Measures

WSDOT shall employ NMFS-approved protected species observers (PSOs) to conduct marine mammal monitoring for its US 101/Chehalis River Bridge-Scour Repair Project. The purposes of marine mammal monitoring are to implement mitigation measures and learn more about impacts to marine mammals from WSDOT’s construction activities. The PSOs will observe and collect data on marine mammals in and around the project area for 30 minutes before, during, and for 30 minutes after all pile removal and pile installation work. NMFS-approved PSOs shall meet the following requirements:

1. Independent observers (i.e., not construction personnel) are required;
2. At least one observer must have prior experience working as an observer;
3. Other observers may substitute education (undergraduate degree in biological science or related field) or training for experience;
4. Where a team of three or more observers are required, one observer...
should be designated as lead observer or monitoring coordinator. The lead observer must have prior experience working as an observer; and

5. NMFS will require submission and approval of observer CVs.

WSDOT must ensure that observers have the following additional qualifications:

1. Ability to conduct field observations and collect data according to assigned protocols;
2. Experience or training in the field identification of marine mammals, including the identification of behaviors;
3. Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
4. Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and duration of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and

5. Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Monitoring of marine mammals around the construction site shall be conducted using high-quality binoculars (e.g., Zeiss, 10 x 42 power). Due to the different sizes of monitoring zones from different pile types, separate zones and monitoring protocols corresponding to each specific pile type will be established.

For vibratory pile driving and pile removal of sheet piles, a total of four land-based PSOs will monitor the shutdown and Level B harassment zones. For vibratory pile driving and pile removal of H piles and timber piles, a total of three land-based PSOs will monitor the shutdown and Level B harassment zones.

Reporting Measures

WSDOT is required to submit a draft monitoring report within 90 days after completion of the construction work or the expiration of the IHA (if issued), whichever comes earlier. This report would detail the monitoring protocol, summarize the data recorded during monitoring, and estimate the number of marine mammals that may have been harassed. NMFS would have an opportunity to provide comments on the report. If NMFS has comments, WSDOT would address the comments and submit a final report to NMFS within 30 days. Reports shall contain, at minimum, the following:

- Date and time that monitored activity begins and ends for each daily conducted (monitoring period);
- Construction activities occurring during each daily observation period, including how many and what type of piles driven;
- Deviation from initial proposal in pile numbers, pile types, average driving times, etc.
- Weather parameters in each monitoring period (e.g., wind speed, percent cloud cover, visibility);
- Water conditions in each monitoring period (e.g., sea state, tide state);
- For each marine mammal sighting:
  - Species, numbers, and, if possible, sex and age class of marine mammals;
  - Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;
  - Location and distance from pile driving activity of marine mammals and distance from the marine mammals to the observation point;
  - Estimated amount of time that the animals remained in the Level B harassment zone;
  - Description of implementation of mitigation measures within each monitoring period (e.g., shutdown or delay);
- Other human activity in the area within each monitoring period;
- A summary of the following:
  - Total number of individuals of each species detected within the Level B harassment zone;
  - Total number of individuals of each species detected within the shutdown zone and the average amount of time that they remained in that zone; and
  - Daily average number of individuals of each species (differentiated by month as appropriate) detected within the Level B harassment zone.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (i.e., population-level effects). An estimate of the number of takes is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be “taken” through harassment, NMFS considers other factors, such as the likely nature of any responses (e.g., intensity, duration), the context of any responses (e.g., critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS’s implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (e.g., as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

NMFS has identified key qualitative and quantitative factors which may be employed to assess the level of analysis necessary to conclude whether potential impacts associated with a specified activity should be considered negligible. These include (but are not limited to) the type and magnitude of taking, the amount and importance of the available habitat for the species or stock that is affected, the duration of the anticipated effect to the species or stock, and the status of the species or stock. When an evaluation of key factors shows that the anticipated impacts of the specified activity would clearly result in no greater than a negligible impact on all affected species or stocks, additional evaluation is not required. In this case, the following factors are in place for all affected species or stocks:

- No takes by Level A harassment are anticipated or authorized;
- Takes by Level B harassment constitute less than 5% of the best available abundance estimates for all stocks;
- Take would not occur in places and/or times where take would be more likely to accrue to impacts on reproduction or survival, such as within ESA-designated or proposed critical habitat, biologically important areas (BIA), or other habitats critical to recruitment or survival (e.g., rookery);
- Take would occur over a short timeframe (less than 30 days of active pile driving required during the IHA effective period);
- Take would occur over <25% of species/stock range; and
- Stock is not known to be declining or suffering from known contributors to
Proposed Authorization
the ESA is not required for this action.
formal consultation under section 7 of
Endangered Species Act (ESA)
subsistence purposes.
such species or stocks for taking for
adverse impact on the availability of
stocks would not have an unmitigable
the total taking of affected species or
stocks.

Small Numbers
As noted above, only small numbers of incidental take may be authorized
under Sections 101(a)(5)(A) and (D) of the MMPA for specified activities other
than military readiness activities. The MMPA does not define small numbers
and so, in practice, where estimated numbers are available, NMFS compares
the number of individuals taken to the most appropriate estimation of
abundance of the relevant species or stock in our determination of whether
an authorization is limited to small numbers of marine mammals.

Additionally, other qualitative factors may be considered in the analysis, such as
the temporal or spatial scale of the activities.

NMFS has estimated that take for all species authorized is less than two
percent of their respective stock abundance (Table 7). Based on the
analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination
There are no relevant subsistence uses of the affected marine mammal stocks or
species implicated by this action. Therefore, NMFS has determined that
the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)
No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Proposed Authorization
As a result of these preliminary determinations, NMFS proposes to issue
an IHA to WSDOT for conducting US 101/Chehalis River Bridge-Scour Repair
Project between July 15, 2019, and February 15, 2020, provided the
previously mentioned mitigation, monitoring, and reporting requirements are incorporated. This section contains a draft of the IHA itself. The wording contained in this section is proposed for inclusion in the IHA (if issued).

1. This Authorization is valid from July 15, 2019, through February 15, 2020.

2. This Authorization is valid only for activities associated with in-water construction work at the US 101/Chehalis River Bridge-Scour Repair Project in the State of Washington.

3. General Conditions.

(a) A copy of this IHA must be in the possession of WSDOT, its designees, and work crew personnel operating under the authority of this IHA.
(b) The species and number of authorized Level B harassment takes are provided in Table 7.
(c) The taking by serious injury or death of any of the species listed in condition 3(b), or any taking of any other species of marine mammal not listed in condition 3(b) of the Authorization is prohibited and may result in the modification, suspension, or revocation of this IHA.
(d) WSDOT must establish and monitor shutdown zone and Level B harassment zones:
(i) Shutdown zone sizes for various pile driving activities and marine mammal hearing groups are shown in Table 8.
(ii) Level B harassment zone sizes are shown in Table 3.

(e) If a marine mammal approaches or enters the shutdown zone (Table 8) during activities other than pile driving, all pile driving activities at that location must be halted or delayed, respectively. If pile driving is halted or delayed due to the presence of a marine mammal, the activity may not resume or commence until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or 15 minutes have passed without re-detection of the animal. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than thirty minutes.
(f) WSDOT must establish monitoring locations and protocols as described below. Please also refer to the Marine Species Monitoring Plan (Monitoring Plan; attached).
(i) For vibratory pile driving of sheet piles, a total of four land-based PSOs must monitor the shutdown zone and Level B harassment zone as depicted in the Monitoring Plan.
(ii) For vibratory pile removal of timber piles and vibratory installation and removal of H piles, a total of three land-based PSOs must monitor the shutdown and Level B harassment zones.

5. Monitoring.
The holder of this Authorization is required to conduct marine mammal monitoring during pile driving and removal.

(a) Monitoring during pile driving and removal must be conducted by NMFS-approved PSOs in a manner consistent with the following:
(i) Independent PSOs (i.e., not construction personnel) who have no other assigned tasks during monitoring periods must be used.
(ii) At least one PSO must have prior experience working as a marine mammal observer during construction activities. Other PSOs may substitute education (degree in biological science or related field) or training for experience.
(iii) Where a team of three or more
PSOs are required, a lead observer or
monitoring coordinator must be
designated. The lead observer must have prior experience working as a marine mammal observer during construction.
iv. WSDOT must submit PSO CVs for approval by NMFS prior to the onset of pile driving.

v. WSDOT must ensure that observers have the following additional qualifications:
   a. Ability to conduct field observations and collect data according to assigned protocols.
   b. Experience or training in the field identification of marine mammals, including the identification of behaviors.
   c. Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations.
   d. Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior.
   e. Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

6. Reporting.

The holder of this Authorization is required to submit marine mammal monitoring and acoustic reports:

(a) WSDOT must submit a draft report on all marine mammal monitoring conducted under this Authorization within ninety calendar days following the completion of monitoring. A final report must be submitted within thirty days following resolution of comments on the draft report from NMFS. The marine mammal monitoring report must contain, at minimum, the informational elements described below:
   i. Date and time that monitored activity begins and ends for each day conducted (monitoring period);
   ii. Construction activities occurring during each daily observation period, including how many and what type of piles driven;
   iii. Deviation from initial proposal in pile numbers, pile types, average driving times, etc.
   iv. Weather parameters in each monitoring period (e.g., wind speed, percent cloud cover, visibility);
   v. Water conditions in each monitoring period (e.g., sea state, tide state);
   vi. For each marine mammal sighting:
      a. Species, numbers, and, if possible, sex and age class of marine mammals;
      b. Description of any observable marine mammal behavior patterns, including bearing and direction of travel and distance from pile driving activity;
      c. Location and distance from pile driving activities to marine mammals and distance from the marine mammals to the observation point;
      d. Estimated amount of time that the animals remained in the Level B harassment zone;
      e. Weather parameters in each observation and monitoring period (e.g., wind speed, wind direction, Beaufort sea state, cloud cover, and visibility);
      f. Environmental conditions (e.g., wind speed and direction, Beaufort sea state, cloud cover, and visibility);
   vii. For each marine mammal detection:
      a. Total number of individuals of each species detected within the Level B harassment zone.
      b. Total number of individuals of each species detected within the Level A harassment zone and the average amount of time that they remained in that zone.
      c. Daily average number of individuals of each species (differentiated by month as appropriate) detected within the Level B Zone, and estimated as taken, if appropriate.
   (b) Reporting injured or dead marine mammals:
      i. In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by this IHA, such as serious injury, or mortality, WSDOT must immediately cease the specified activities and report the incident to the Office of Protected Resources, NMFS, and the West Coast Region Stranding Coordinator, NMFS. The report must include the following information:
         1. Time and date of the incident;
         2. Description of the incident;
         3. Environmental conditions (e.g., wind speed and direction, Beaufort sea state, cloud cover, and visibility);
         4. Description of all marine mammal observations and active sound source use in the 24 hours preceding the incident;
         5. Species identification or description of the animal(s) involved;
         6. Fate of the animal(s); and
         7. Photographs or video footage of the animal(s).
   Activities must not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with WSDOT to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. WSDOT may not resume their activities until notified by NMFS.
   ii. In the event WSDOT discovers an injured or dead marine mammal, and the lead observer determines that the cause of the injury or death is unknown and the death is relatively recent (e.g., in less than a moderate state of decomposition), WSDOT must immediately report the incident to the Office of Protected Resources, NMFS, and the West Coast Region Stranding Coordinator, NMFS. The report must include the same information identified in 6(b)(i) of this IHA. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with WSDOT to determine whether additional mitigation measures or modifications to the activities are appropriate.
   iii. In the event that WSDOT discovers an injured or dead marine mammal, and the lead observer determines that the injury or death is not associated with or related to the activities authorized in the IHA (e.g., previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), WSDOT must report the incident to the Office of Protected Resources, NMFS, and the West Coast Region Stranding Coordinator, NMFS, within 24 hours of the discovery. WSDOT must provide photographs or video footage or other documentation of the stranded animal sighting to NMFS.

7. This Authorization may be modified, suspended, or withdrawn if the holder fails to abide by the conditions prescribed herein, or if NMFS determines the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this Notice of Proposed IHA for the proposed project. We also request comment on the potential for renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization.

On a case-by-case basis, NMFS may issue a second one-year IHA without additional notice when (1) another year of identical or nearly identical activities as described in the Specified Activities section is planned or (2) the activities would not be completed by the time the IHA expires and a second IHA would allow for completion of the activities beyond that described in the Dates and Duration section, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to expiration of the current IHA;
DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG549

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice of intent to prepare a Draft Supplemental Environmental Impact Statement.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA), this notice announces that NMFS is preparing a Draft Supplemental Environmental Impact Statement (DSEIS) to supplement information in the 2017 Draft Environmental Impact Statement (DEIS) for 10 Hatchery and Genetic Management Plans (HGMP) for salmon and steelhead hatchery programs jointly submitted by the Washington Department of Fish and Wildlife (WDFW) with the Muckleshoot Indian Tribe and the Suquamish Tribe (referred to as the co-managers), for NMFS’s evaluation and determination under Limit 6 of the Endangered Species Act (ESA) 4(d) Rule for threatened salmon and steelhead. The HGMPs specify the propagation of salmon and steelhead in the Duwamish-Green River basin in Washington State. The DSEIS will analyze an additional alternative reflecting an increase in hatchery production of juvenile Chinook salmon.

DATES: Because NMFS has previously requested (81 FR 26776, May 6, 2016) and received information from the public on issues to be addressed in the EIS, and because the Council on Environmental Quality (CEQ) regulations for implementing the National Environmental Policy Act (NEPA) do not require additional scoping for this DSEIS process (40 CFR 1502.9(c)(4)), NMFS is not asking for further public scoping information and comment at this time. Upon release of the DSEIS, NMFS will provide a 45-day public review/comment period.


FOR FURTHER INFORMATION CONTACT: Steve Leider, NMFS, by phone at (360) 753–4650, or email to steve.leider@noaa.gov.

SUPPLEMENTARY INFORMATION:

Background

The WDFW, and the co-managers have jointly submitted to NMFS HGMPs for 10 hatchery programs in the Duwamish-Green River basin in Washington State. The HGMPs reviewed in the DEIS were submitted to NMFS from 2013 to 2015, pursuant to limit 6 of the 4(d) Rule for salmon and steelhead. The hatchery programs include releases of ESA-listed Chinook salmon and winter-run steelhead into the Duwamish-Green River basin. The hatchery programs also release non-listed coho and fall-run chum salmon and summer-run steelhead into the Duwamish-Green River basin. One hatchery program releases coho salmon into marine waters adjacent to the Duwamish-Green River basin. Seven of the programs are currently operating, and three are new.

NEPA requires Federal agencies to conduct environmental analyses of their proposed major actions to determine if the actions may affect the human environment. NMFS’s action of determining that implementation of the co-managers’ HGMPs would not appreciably reduce the likelihood of survival and recovery of affected threatened ESUs under Limit 6 of the 4(d) Rule for salmon and steelhead promulgated under the ESA, is a major Federal action subject to environmental review under NEPA.

On May 4, 2016, NMFS announced its intent to prepare an EIS and the 30-day public scoping period ended on June 3, 2016. On November 3, 2017, NMFS announced the release of a DEIS for public comment. The DEIS includes an analysis of the proposed action identified in the 2016 NOI and the anticipated environmental impacts. Following an extension, the 75-day public comment period ended on January 19, 2018.

In light of subsequent information, NMFS has determined that the Final EIS would benefit from the analysis of an expanded range of potential alternatives for hatchery production of Chinook salmon. The alternative to be analyzed in the DSEIS is informed by the applicant’s interest in increasing hatchery production of juvenile Chinook salmon, and NMFS’ analysis of the status of endangered Southern Resident Killer Whales and the importance of Chinook salmon prey to their food base. The DSEIS will analyze an increased level of Chinook salmon hatchery production and provide the public with an opportunity for review and comment. The DSEIS, in conjunction with the 2017 DEIS, will collectively evaluate the proposed action and alternatives.

Alternatives

The alternatives analyzed in the 2017 DEIS are summarized in the DEIS Notice of Intent (82 FR 26776, May 4, 2016). The upcoming DSEIS will analyze an alternative in which hatchery production from the Soos Creek Chinook salmon program would produce an additional 2,000,000 juvenile Chinook salmon to be released at Palmer Ponds in the Duwamish-Green River basin.

Authority

The environmental review of the 10 salmon and steelhead HGMPs in the Duwamish-Green River basin of Washington State will be conducted in accordance with requirements of the NEPA of 1969 as amended (42 U.S.C. 4321 et seq.), NEPA Regulations (40 CFR parts 1500–1508), other appropriate Federal laws and regulations, and policies and procedures of NMFS for compliance with those regulations.
O’Day Act (41 U.S.C. 8501–8506) in connection with the product and services deleted from the Procurement List.

End of Certification

Accordingly, the following product and services are deleted from the Procurement List:

<table>
<thead>
<tr>
<th>Product</th>
<th>NSN(s)—Product Name(s):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field Activity Chesapeake, 1314 Harwood Avenue SE, Washington, DC</td>
<td>6545–00–853–6309—First Aid Kit, Eye Dressing</td>
</tr>
<tr>
<td>Action: Mandatory Source of Supply: Suburban Adult Services, Inc., Elma, NY</td>
<td></td>
</tr>
<tr>
<td>Services</td>
<td>Contracting Activity: Defense Logistics Agency Troop Support</td>
</tr>
<tr>
<td>Service Type: Reproduction and Courier Service</td>
<td></td>
</tr>
<tr>
<td>Mandatory for: Naval Facilities Engineering Command,</td>
<td></td>
</tr>
<tr>
<td>Naval Air Warfare Center Weapons Division: Buildings 456 (N97) and 1438</td>
<td></td>
</tr>
<tr>
<td>Mandatory Source of Supply: U.S. FLEET FORCES COMMAND</td>
<td></td>
</tr>
<tr>
<td>Service Type: Grounds Maintenance Service</td>
<td></td>
</tr>
<tr>
<td>Mandatory for: Naval &amp; Marine Corps Reserve Center (NMCRC),</td>
<td></td>
</tr>
<tr>
<td>Mandatory Source of Supply: NAVFAC SOUTHWEST</td>
<td></td>
</tr>
<tr>
<td>Contracting Activity: DEPT OF THE NAVY, U.S. FLEET FORCES COMMAND</td>
<td></td>
</tr>
<tr>
<td>Contracting Activity: DEPT OF THE NAVY, NAVFAC SOUTHWEST</td>
<td></td>
</tr>
<tr>
<td>Contracting Activity: DEPT OF THE NAVY, U.S. FLEET FORCES COMMAND</td>
<td></td>
</tr>
<tr>
<td>Contracting Activity: DEPT OF THE NAVY, NAVFAC SOUTHWEST</td>
<td></td>
</tr>
</tbody>
</table>

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

PROCUREMENT LIST; DELETIONS

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes a product and services from the Procurement List previously furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Date deleted from the Procurement List: November 18, 2018.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email CMTEFedReg@AbilityOne.gov.

SUPPLEMENTARY INFORMATION:

Deletions

On 9/14/2018 (83 FR 179), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the product and services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action may result in authorizing small entities to furnish the product and services to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-
DEPARTMENT OF EDUCATION [Docket No.: ED–2018–ICCD–0107]

Agency Information Collection Activities; Comment Request; The Department of Education Accrediting Agency, Foreign Medical and Foreign Veterinarian Program Comparability Database Approval

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before December 18, 2018.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use http://www.regulations.gov by searching the Docket ID number ED–2018–ICCD–0107. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at http://www.regulations.gov by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 550 12th Street SW, PCP, Room 9086, Washington, DC 20202–0023.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Herman Bounds, 202–453–6128.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public’s reporting burden. It also helps the public understand the Department’s information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: The Department of Education Accrediting Agency, Foreign Medical and Foreign Veterinarian Program Comparability Database Approval.

OMB Control Number: 1840–0788.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 94.

Total Estimated Number of Annual Burden Hours: 3,988.

Abstract: The United States Secretary of Education (Secretary) is required by law to publish a list of nationally-recognized accrediting agencies that have been determined to be reliable authorities regarding the quality of education or training offered by the institutions or programs they accredit. In determining whether a specific agency should be recognized, the Secretary evaluates the submission for compliance with the Criteria for Recognition contained in regulations. The collection of information is necessary for the Secretary to evaluate and monitor the continued compliance with the criteria during any period of recognition granted. This collection is submitted due to the approaching end of the 3 year approval period. There is a change in burden hours for the following reasons. The number of accrediting agencies/organizations submitting documentation increased. Two additional accrediting agencies submitted initial petitions for recognition and supporting documentation, one additional foreign veterinary accrediting agency and two additional accrediting organizations communicated their intent to submit an initial application. Department staff consulted with seven accrediting agencies and organizations and determined that a new evaluation of burden hours was necessary.


Kate Mullan,
Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2018–22788 Filed 10–18–18; 8:45 am]
BILLING CODE 6353–01–P

DEPARTMENT OF ENERGY Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings


Description: Tariff Amendment: Volume No. 2—BKV Operating LLC Table of Contents Amend to be effective 11/1/2018.

Filed Date: 10/10/18.

Accession Number: 20181010–5101.

Comments Due: 5 p.m. ET 10/22/18.

Docket Numbers: RP19–50–00–000. Applicants: White River Hub, LLC.


Filed Date: 10/11/18.

Accession Number: 20181011–5011.

Comments Due: 5 p.m. ET 10/23/18.


Description: eTariff filing per 1430: FERC Form No. 501–G Report.

Filed Date: 10/11/18.

Accession Number: 20181011–5023.

Comments Due: 5 p.m. ET 10/23/18.


Description: eTariff filing per 1430: GNGS FERC Form 501–G.

Filed Date: 10/11/18.

Accession Number: 20181011–5024.
Comments Due: 5 p.m. ET 10/23/18.


Applicants: Kinetic Energy Express, LLC.

Description: eTariff filing for 1430: Form 501–G.

Filed Date: 10/11/18.

Accession Number: 20181011–5024.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Kinetic Energy Express, LLC.

Description: eTariff filing for 1430: Form 501–G.

Filed Date: 10/11/18.

Accession Number: 20181011–5027.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Kern River Gas Transmission Company.

Description: eTariff filing for 1430: Form 501–G.

Filed Date: 10/11/18.

Accession Number: 20181011–5032.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: MIGC LLC.


Filed Date: 10/11/18.

Accession Number: 20181011–5032.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Algonquin Gas Transmission, LLC.

Description: eTariff filing for 1430: AGT FERC Form 501–G.

Filed Date: 10/11/18.

Accession Number: 20181011–5044.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Limited Section 4 to be effective 12/1/2018.

Filed Date: 10/11/18.

Accession Number: 20181011–5097.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Millennium Pipeline Company, LLC.

Description: § 4(d) Rate Filing: List of Non-Conforming Service Agreements (ASR In-Svc and Misc.) to be effective 11/11/2018.

Filed Date: 10/11/18.

Accession Number: 20181011–5046.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Northern Natural Gas Company.

Description: eTariff filing for 1430: Form 501–G.

Filed Date: 10/11/18.

Accession Number: 20181011–5055.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Vector Pipeline L.P.

Description: eTariff filing for 1430: FERC Form 501–G Filing.

Filed Date: 10/11/18.

Accession Number: 20181011–5070.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Vector Pipeline L.P.

Description: eTariff filing for 1440: Limited Section 4 Tax Reduction Filing to be effective 12/1/2018.

Filed Date: 10/11/18.

Accession Number: 20181101–5073.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Dominion Energy Transmission, Inc.

Description: eTariff filing for 1430: ETNG FERC Form No. 501–G.

Filed Date: 10/11/18.

Accession Number: 20181101–5084.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: East Tennessee Natural Gas, LLC.

Description: eTariff filing for 1440: ETNG Limited Section 4 to be effective 12/1/2018.

Filed Date: 10/11/18.

Accession Number: 20181101–5097.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Millennium Pipeline Company, LLC.

Description: § 4(d) Rate Filing: List of Non-Conforming Service Agreements (ASR In-Svc and Misc.) to be effective 11/11/2018.

Filed Date: 10/11/18.

Accession Number: 20181011–5046.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Northern Natural Gas Company.

Description: eTariff filing for 1430: Form 501–G.

Filed Date: 10/11/18.

Accession Number: 20181011–5055.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Vector Pipeline L.P.

Description: eTariff filing for 1430: FERC Form 501–G Filing.

Filed Date: 10/11/18.

Accession Number: 20181011–5070.

Comments Due: 5 p.m. ET 10/23/18.


Applicants: Vector Pipeline L.P.
Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant’s request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 5, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at http://www.ferc.gov. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding 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.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2018–22822 Filed 10–18–18; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14751–002]

Alpine Pacific Utilities Hydro, LLC;
Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission’s (Commission) regulations, 18 CFR part 380, the Office of Energy Projects has reviewed the original license application for the Fresno Dam Site Water Power Project, located on the Milk River, at the existing U.S. Bureau of Reclamation’s (Reclamation) Fresno Dam, in Hill County, Montana, and has prepared an Environmental Assessment (EA) for the project. The project would occupy 0.07 acre of federal land managed by Reclamation.

The EA contains staff’s analysis of the potential environmental impacts of the project and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment. A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission’s website at http://www.ferc.gov using the “eLibrary” link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at FERCONlineSupport@ferc.gov. (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

You may also register online at http://www.ferc.gov/docs-filing/esubscription.asp to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice.

The Commission strongly encourages electronic filing. Please file comments using the Commission’s eFiling system at http://www.ferc.gov/docs-filing/eFiling.asp. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at http://www.ferc.gov/docs-filing/eComment.asp. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support In lieu of electronic filing, please send a
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: EC19–11–000.
Applicants: Liberty Utilities (CalPeco Electric) LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of Liberty Utilities (CalPeco Electric) LLC.
Filed Date: 10/12/18.
Accession Number: 20181012–5199.
Comments Due: 5:00 p.m. ET 11/2/18.

Docket Numbers: ER18–2029–001.
Applicants: Southern California Edison Company.
Description: Tariff Amendment: SCE’s Response to Deficiency re GIA & DistrbServAgmt AltuGas SA Nos. 1027–1028 to be effective 7/18/2018.
Filed Date: 10/15/18.
Accession Number: 20181015–5085.
Comments Due: 5:00 p.m. ET 11/5/18.
Docket Numbers: ER19–104–000.
Applicants: Duke Energy Ohio, Inc., PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Revised Tariff Sheets for Recovery of 2019 Admin. Costs to be effective 1/1/2019.
Filed Date: 10/15/18.
Accession Number: 20181015–5067.
Comments Due: 5:00 p.m. ET 11/5/18.
Docket Numbers: ER19–103–000.
Description: § 205(d) Rate Filing: Duke Energy Ohio submits IA SA No. 5186 and Cancellation of IA SA No. 1958 to be effective 6/30/2018.
Filed Date: 10/15/18.
Accession Number: 20181015–5068.
Comments Due: 5:00 p.m. ET 11/5/18.
Applicants: SCE’s Response to Deficiency re GIA & DistrbServAgmt AltuGas SA Nos. 1027–1028 to be effective 7/18/2018.
Filed Date: 10/12/18.
Accession Number: 20181012–5177.
Comments Due: 5:00 p.m. ET 11/2/18.

Applicants: Birdsboro Power LLC.
Description: Baseline eTariff Filing: Application for Market Based Rate to be effective 12/1/2018.
Filed Date: 10/15/18.
Accession Number: 20181015–5048.
Comments Due: 5:00 p.m. ET 11/5/18.
Applicants: ISO New England Inc.
Filed Date: 10/15/18.
Accession Number: 20181015–5061.
Comments Due: 5:00 p.m. ET 11/5/18.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to WMPA SA No. 4916; Queue No. AC2–070 to be effective 1/26/2018.
Filed Date: 10/15/18.
Accession Number: 20181015–5066.
Comments Due: 5:00 p.m. ET 11/5/18.
Applicants: Duke Energy Ohio, Inc., PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Revised Tariff Sheets for Recovery of Costs for the 2019 Operation of NESCOE to be effective 1/1/2019.
Filed Date: 10/15/18.
Accession Number: 20181015–5069.
Comments Due: 5:00 p.m. ET 11/5/18.
Applicants: KCP&L Greater Missouri Operations Company.
Description: Application under Section 204 of the Federal Power Act for Authorization to Issue Securities of KCP&L Greater Missouri Operations Company.
Filed Date: 10/12/18.
Accession Number: 20181012–5176.
Comments Due: 5:00 p.m. ET 11/2/18.
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.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9041–8]

Environmental Impact Statements; Notice of Availability

Weekly receipt of Environmental Impact Statements
Filed 10/08/2018 Through 10/12/2018
Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA’s comment letters on EISs are available at: https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.
EIS No. 20180245, Draft, FRA, OR, Oregon Passenger Rail Tier 1 Draft Environmental Impact Statement, Comment Period Ends: 12/18/2018, Contact: Lydia Kakadoorian 781–227–0778
EIS No. 20180246, Draft, FERC, TX, Rio Grande LNG Project, Comment Period Ends: 12/03/2018, Contact: Office of External Affairs 866–206–3372
EIS No. 20180247, Draft, USFWS, FL, Eastern Collier Multiple Species Incidental Take Permit Applications and Habitat Conservation Plan,
Comment Period Ends: 12/03/2018, Contact: David Dell 404–679–7313

Amended Notices
EIS No. 20180238, Final, UDOT, UT, S.R. 30, S.R. 23 to 1000 West, Contact: Naomi Kisen 801–965–4005 Revision to the FR Notice Published 10/12/2018; Correcting Lead Agency from FHWA to UDOT.
Robert Tomiak, Director, Office of Federal Activities.

ENVIROMENTAL PROTECTION AGENCY
[FR Doc. 2018–22745 Filed 10–18–18; 8:45 am
BILLING CODE 6560–50–P]

Pesticide Registration Maintenance Fee: Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations
AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by registrants through Pesticide Registration Maintenance Fee responses to voluntarily cancel certain pesticide registrations. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw its requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registrations have been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before November 19, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2018–0657, 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.

Submit written withdrawal request by mail to: Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. ATTN: Michael Yanchulis.

• 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: Michael Yanchulis, Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 347–0237; email address: yanchulis.michael@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information
A. Does this action apply to me?
This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides.

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. What action is the Agency taking?
This notice announces receipt by the Agency of requests from registrants to cancel 200 pesticide products registered under FIFRA section 3 (7 U.S.C. 136a) or 24(c) (7 U.S.C. 136v(c)). These registrations are listed in sequence by registration number (or company number and 24(c) number) in Table 1 of this unit.

Unless the Agency determines that there are substantive comments that warrant further review of the requests or the registrants withdraw their requests, EPA intends to issue an order in the Federal Register canceling all of the affected registrations.

I. General Information
A. Does this action apply to me?
This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides.

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. What action is the Agency taking?
This notice announces receipt by the Agency of requests from registrants to cancel 200 pesticide products registered under FIFRA section 3 (7 U.S.C. 136a) or 24(c) (7 U.S.C. 136v(c)). These registrations are listed in sequence by registration number (or company number and 24(c) number) in Table 1 of this unit.

Unless the Agency determines that there are substantive comments that warrant further review of the requests or the registrants withdraw their requests, EPA intends to issue an order in the Federal Register canceling all of the affected registrations.

TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

<table>
<thead>
<tr>
<th>Registration No.</th>
<th>Company No.</th>
<th>Product name</th>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>100–1053</td>
<td>100</td>
<td>Havoc Rodenticide Bait Pack Pellets with Bitrex</td>
<td>Brodifacoum.</td>
</tr>
<tr>
<td>100–1054</td>
<td>100</td>
<td>Havoc Rodenticide Bait Pack Mini-Pellets with Bitrex</td>
<td>Brodifacoum.</td>
</tr>
<tr>
<td>100–1065</td>
<td>100</td>
<td>Scimitar WP Insecticide in Water-Soluble Packs</td>
<td>lambda-Cyhalothrin.</td>
</tr>
<tr>
<td>100–1082</td>
<td>100</td>
<td>Demand Pestab Insecticide</td>
<td>lambda-Cyhalothrin.</td>
</tr>
<tr>
<td>100–1142</td>
<td>100</td>
<td>Mesotrine/acetochlor 3.5 CS</td>
<td>Mesotrine; Acetochlor.</td>
</tr>
<tr>
<td>100–1152</td>
<td>100</td>
<td>Lumax Selective Herbicide</td>
<td>Mesotrine; Atrazine; S-Metolachlor.</td>
</tr>
<tr>
<td>100–1174</td>
<td>100</td>
<td>Impasse Termite Bait</td>
<td>Lufenuron.</td>
</tr>
<tr>
<td>Registration No.</td>
<td>Company No.</td>
<td>Product name</td>
<td>Chemical name</td>
</tr>
<tr>
<td>-----------------</td>
<td>------------</td>
<td>--------------</td>
<td>---------------</td>
</tr>
<tr>
<td>100–1181</td>
<td>100</td>
<td>Zyro Plus Termite Baiting Technology</td>
<td>Lufenuron.</td>
</tr>
<tr>
<td>100–1201</td>
<td>100</td>
<td>Lexar Herbicide</td>
<td>Mesotrione; Atrazine; S-Metolachlor.</td>
</tr>
<tr>
<td>100–1257</td>
<td>100</td>
<td>Lufenuron Termite Bait</td>
<td>Lufenuron.</td>
</tr>
<tr>
<td>100–1396</td>
<td>100</td>
<td>Flexstar GT Manufacturing Use Concentrate</td>
<td>Glyphosate; Sodium salt of fomesafen.</td>
</tr>
<tr>
<td>100–1436</td>
<td>100</td>
<td>Derby</td>
<td>Thiamethoxam; lambda-Cyhalothrin.</td>
</tr>
<tr>
<td>100–1542</td>
<td>100</td>
<td>Zyro SC</td>
<td>Cyantraniliprole.</td>
</tr>
<tr>
<td>228–689</td>
<td>228</td>
<td>MSM E-Pro 60 EG Herbicide</td>
<td>Metsulfuron.</td>
</tr>
<tr>
<td>228–702</td>
<td>228</td>
<td>Nufarm Prosedge Selective Herbicide</td>
<td>Halosulfuron-methyl.</td>
</tr>
<tr>
<td>264–1075</td>
<td>264</td>
<td>Wolverine Herbicide</td>
<td>Bromoxynil octanoate; Bromoxynil heptanoate; Fenoxaprop-p-ethyl; Pyrasulfotole Technical.</td>
</tr>
<tr>
<td>264–1103</td>
<td>264</td>
<td>Atlantis Herbicide</td>
<td>Mesosulfuron-methyl; Iodosulfuron-methyl-sodium.</td>
</tr>
<tr>
<td>270–307</td>
<td>270</td>
<td>Farnam Pet Spray 549</td>
<td>MNG 264; Pyrethrins; Pyriproxyfen.</td>
</tr>
<tr>
<td>400–583</td>
<td>400</td>
<td>Captain Technical</td>
<td>Captain.</td>
</tr>
<tr>
<td>400–599</td>
<td>400</td>
<td>Fluro-Technical</td>
<td>Flumetralin.</td>
</tr>
<tr>
<td>432–1232</td>
<td>432</td>
<td>Chipco 26019 75WDG Brand Fungicide</td>
<td>Iprodione.</td>
</tr>
<tr>
<td>432–1588</td>
<td>432</td>
<td>Linear Herbicide</td>
<td>Aminocyclopyrachlor; Sulfometuron; Chlorsulfuron.</td>
</tr>
<tr>
<td>432–1577</td>
<td>432</td>
<td>Lineage HWC Herbicide</td>
<td>Imazapyr; Sulfometuron; Metsulfuron.</td>
</tr>
<tr>
<td>432–1576</td>
<td>432</td>
<td>Lineage Prep Herbicide</td>
<td>Imazapyr; Sulfometuron; Metsulfuron.</td>
</tr>
<tr>
<td>875–41</td>
<td>875</td>
<td>Diversol Cx with Arodyne</td>
<td>Sodium hypochlorite.</td>
</tr>
<tr>
<td>875–95</td>
<td>875</td>
<td>Low Temperature Sanitizer W500I</td>
<td>Sodium hypochlorite.</td>
</tr>
<tr>
<td>875–182</td>
<td>875</td>
<td>Divosan X-Tend</td>
<td>Phosphoric acid.</td>
</tr>
<tr>
<td>875–185</td>
<td>875</td>
<td>Pro-Kleen</td>
<td>Phosphoric acid; Dodecylbenzenesulfonic acid.</td>
</tr>
<tr>
<td>1015–67</td>
<td>1015</td>
<td>Douglas Pyrethrins 5</td>
<td>MNG 264; Piperonyl butoxide; Pyrethrins.</td>
</tr>
<tr>
<td>2596–814</td>
<td>2596</td>
<td>Hartz 2 in 1 Flea &amp; Tick Dip for Dogs with Pyrethrin</td>
<td>Piperonyl butoxide; Pyrethrins.</td>
</tr>
<tr>
<td>2724–640</td>
<td>2724</td>
<td>Speer Neoperm Wasp &amp; Hornet Killer #1</td>
<td>Piperonyl butoxide; Permethrin; Tetramethrin.</td>
</tr>
<tr>
<td>2724–646</td>
<td>2724</td>
<td>Speer Neoperm Crowing Insect Killer IV</td>
<td>Piperonyl butoxide; Permethrin; Tetramethrin.</td>
</tr>
<tr>
<td>3862–135</td>
<td>3862</td>
<td>Drop Dead</td>
<td>Propoxur; MNG 264; Piperonyl butoxide; Pyrethrins.</td>
</tr>
<tr>
<td>3862–156</td>
<td>3862</td>
<td>Microbiocide LD-5</td>
<td>Potassium dimethylthiocarbamate.</td>
</tr>
<tr>
<td>5383–88</td>
<td>5383</td>
<td>Troyan Polyphase 588</td>
<td>Carbamic acid, butyl-3, 2-propynyl ester; Irgarol 1051.</td>
</tr>
<tr>
<td>5383–102</td>
<td>5383</td>
<td>Mergal S90</td>
<td>Carbendazim; Oxolinone; Irgarol 1051.</td>
</tr>
<tr>
<td>5383–115</td>
<td>5383</td>
<td>Polyphase 3000</td>
<td>Carbamic acid, butyl-3, 2-propynyl ester.</td>
</tr>
<tr>
<td>5383–167</td>
<td>5383</td>
<td>Nuosept Bit Technical</td>
<td>1,2-Benzisothiazolin-3-one.</td>
</tr>
<tr>
<td>5736–102</td>
<td>5736</td>
<td>Super-Bol</td>
<td>Quaternary Ammonium Compounds.</td>
</tr>
<tr>
<td>5813–52</td>
<td>5813</td>
<td>Ultra Clorox Brand 6.15% Bleach</td>
<td>Sodium hypochlorite.</td>
</tr>
<tr>
<td>5916–70</td>
<td>5916</td>
<td>The Andersons Weed &amp; Feed</td>
<td>2,4-D, dimethylamine salt.</td>
</tr>
<tr>
<td>5916–79</td>
<td>5916</td>
<td>The Andersons Tee Time Fertilizer with 1.15% Team</td>
<td>Benfluralin; Trifluralin.</td>
</tr>
<tr>
<td>5916–111</td>
<td>5916</td>
<td>The Andersons 1.0% Bayer(R) Rungicide</td>
<td>Triadimefon.</td>
</tr>
<tr>
<td>5916–184</td>
<td>5916</td>
<td>Andersons Golf Products Kog Weed Control</td>
<td>Dicamba.</td>
</tr>
<tr>
<td>5916–201</td>
<td>5916</td>
<td>High K Fertilizer with TGR POA Annual Control</td>
<td>Paclobutrazol.</td>
</tr>
<tr>
<td>5916–216</td>
<td>5916</td>
<td>The Andersons 0.058% Granular Bifenthrin Insecticide 0.058%</td>
<td>Bifenthrin.</td>
</tr>
<tr>
<td>11556–164</td>
<td>11556</td>
<td>Americare Rabon Flea &amp; Tick Collar for Dogs</td>
<td>Gardona (cis-isomer).</td>
</tr>
<tr>
<td>11556–165</td>
<td>11556</td>
<td>Americare Rabon Flea &amp; Tick Collar for Cats</td>
<td>Gardona (cis-isomer).</td>
</tr>
<tr>
<td>28293–146</td>
<td>28293</td>
<td>Unicon Concentrated Flea and Tick Dip</td>
<td>MNG 264; Piperonyl butoxide; Pyrethrins.</td>
</tr>
<tr>
<td>28293–158</td>
<td>28293</td>
<td>Unicon Knockdown Spray</td>
<td>MNG 264; Permethrin; Pyrethrins.</td>
</tr>
<tr>
<td>28293–161</td>
<td>28293</td>
<td>Unicon Home Fogger</td>
<td>MNG 264; Permethrin; Pyrethrins.</td>
</tr>
<tr>
<td>28293–214</td>
<td>28293</td>
<td>Unicon IGR Total Release Fogger</td>
<td>MNG 264; Permethrin; Pyriproxyfen; Pyrethrins.</td>
</tr>
<tr>
<td>53883–245</td>
<td>53883</td>
<td>Diuron 4L Algaecide</td>
<td>Diuron.</td>
</tr>
<tr>
<td>55146–150</td>
<td>55146</td>
<td>NUP-12103 Bulk Product</td>
<td>Azoxylosin; Propiconazole.</td>
</tr>
<tr>
<td>60063–27</td>
<td>60063</td>
<td>Syccam Propiconazole 1.3ME</td>
<td>Propiconazole.</td>
</tr>
<tr>
<td>66222–96</td>
<td>66222</td>
<td>Diuron 90DF</td>
<td>Diuron.</td>
</tr>
<tr>
<td>66222–170</td>
<td>66222</td>
<td>Rotary 2 SL</td>
<td>Diuron.</td>
</tr>
<tr>
<td>66330–377</td>
<td>66330</td>
<td>Thifensulfuron + Triburon 4:1 Herbicide Tank Mix</td>
<td>Thifensulfuron.</td>
</tr>
<tr>
<td>66330–378</td>
<td>66330</td>
<td>Thifensulfuron + Triburon 2:1 Herbicide Tank Mix</td>
<td>Thifensulfuron; Triburon-methyl.</td>
</tr>
<tr>
<td>66330–405</td>
<td>66330</td>
<td>Raze Herbicide</td>
<td>Fluroxypyr 1-methylheptyl ester; Flucarbazone-sodium.</td>
</tr>
<tr>
<td>66330–426</td>
<td>66330</td>
<td>Dicamba Technical</td>
<td>Dicamba.</td>
</tr>
<tr>
<td>66719–7</td>
<td>66719</td>
<td>CPPC Ultra Bleach</td>
<td>Sodium hypochlorite.</td>
</tr>
<tr>
<td>68156–4</td>
<td>68156</td>
<td>Dintef HFP Trifluralin</td>
<td>Trifluralin.</td>
</tr>
<tr>
<td>69681–33</td>
<td>69681</td>
<td>Cloo Mor Multishock Plus</td>
<td>Sodium dichloro-s-triazinetrione.</td>
</tr>
<tr>
<td>69961–34</td>
<td>69961</td>
<td>Cloo Mor Triple-Action Chlorinating Tabs</td>
<td>Trichloro-s-triazinetrione; Boron sodium oxide (B4Na2O7), pentahydrate.</td>
</tr>
<tr>
<td>70627–4</td>
<td>70627</td>
<td>Johnson CRS</td>
<td>Sodium hypochlorite.</td>
</tr>
<tr>
<td>70627–51</td>
<td>70627</td>
<td>Raid Commercial Flying Insect Killer</td>
<td>Piperonyl butoxide; Tetramethrin.</td>
</tr>
<tr>
<td>70627–6</td>
<td>70627</td>
<td>Multi-Surface Antibacterial</td>
<td>L-Lactic acid.</td>
</tr>
<tr>
<td>70627–76</td>
<td>70627</td>
<td>Windex Multi-Surface Disinfectant</td>
<td>L-Lactic acid.</td>
</tr>
<tr>
<td>72155–10</td>
<td>72155</td>
<td>Merit 0.005% PM Plus Fertilizer</td>
<td>Imidacloprid.</td>
</tr>
<tr>
<td>72155–34</td>
<td>72155</td>
<td>Beta-Cyfluthrin 0.05% Fire Ant Granular Insecticide</td>
<td>Beta-Cyfluthrin.</td>
</tr>
<tr>
<td>72155–44</td>
<td>72155</td>
<td>Merit 0.2 Granular Insecticide</td>
<td>Imidacloprid.</td>
</tr>
<tr>
<td>72155–61</td>
<td>72155</td>
<td>Tebuconazole 1.0% + Merit 0.2% Concent rate Fungicide/Insecticide</td>
<td>Tebuconazole; Imidacloprid.</td>
</tr>
</tbody>
</table>
### TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

<table>
<thead>
<tr>
<th>Registration No.</th>
<th>Company No.</th>
<th>Product name</th>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>72155–89</td>
<td>72155</td>
<td>Lawn 3FL Herbicide Concentrate/Ready-To-Spray</td>
<td>2,4-D, dimethylamine salt; Mecoprop-P; Dicamba, potassium salt; Indaziflam.</td>
</tr>
<tr>
<td>72155–90</td>
<td>72155</td>
<td>Lawn 3FL Herbicide Ready-To-Use</td>
<td>2,4-D, dimethylamine salt; Mecoprop-P; Dicamba, potassium salt; Indaziflam.</td>
</tr>
<tr>
<td>72155–104</td>
<td>72155</td>
<td>Lawn 3FL2 Herbicide Concentrate/Ready-To-Spray</td>
<td>2,4-D, dimethylamine salt; Mecoprop-P; Dicamba, potassium salt; Indaziflam.</td>
</tr>
<tr>
<td>72155–105</td>
<td>72155</td>
<td>Lawn 3FL2 Herbicide Ready-To-Use</td>
<td>2,4-D, dimethylamine salt; Mecoprop-P; Dicamba, potassium salt; Indaziflam.</td>
</tr>
<tr>
<td>72304–8</td>
<td>72304</td>
<td>Clortramid F–54</td>
<td>Dicamba, diglycolamine salt.</td>
</tr>
<tr>
<td>83070–10</td>
<td>83070</td>
<td>Eject 4L</td>
<td>Quinclorac.</td>
</tr>
<tr>
<td>85588–11</td>
<td>85588</td>
<td>Pysone Carbamid</td>
<td>Pyrithiobac-sodium.</td>
</tr>
<tr>
<td>AL170004</td>
<td>352</td>
<td>Dupont Fexapan Herbicide</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>AR080001</td>
<td>352</td>
<td>Dupont Firstshot SG Bumdown Herbicide</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>AR100005</td>
<td>8033</td>
<td>Confirm 2F Agricultural Insecticide</td>
<td>Tebufenozide.</td>
</tr>
<tr>
<td>AR120008</td>
<td>59639</td>
<td>V–10142 AG Herbicide</td>
<td>Imazosulfuron.</td>
</tr>
<tr>
<td>AR130001</td>
<td>352</td>
<td>Dupont Realm Q Herbicide</td>
<td>Mesotrione; Rimsulfuron.</td>
</tr>
<tr>
<td>AR140004</td>
<td>8033</td>
<td>Intruder Brand Insecticide</td>
<td>Acetamiprid.</td>
</tr>
<tr>
<td>AR940002</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>AR940003</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>AR950004</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>AZ110002</td>
<td>7173</td>
<td>Difethialone Paste Place Packs</td>
<td>Difethialone.</td>
</tr>
<tr>
<td>AZ120003</td>
<td>10163</td>
<td>Intruder Brand Insecticide</td>
<td>Acetamiprid.</td>
</tr>
<tr>
<td>AZ170005</td>
<td>8033</td>
<td>Assail 70WP Insecticide</td>
<td>Acetamiprid.</td>
</tr>
<tr>
<td>CA040027</td>
<td>5481</td>
<td>Alco Citrus Fix</td>
<td>2,4-D, isopropyl ester.</td>
</tr>
<tr>
<td>CA100007</td>
<td>34704</td>
<td>Liqui-Stik Concentrate</td>
<td>Ammonium 1-naphthaleneacetate.</td>
</tr>
<tr>
<td>CA930003</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>CA930013</td>
<td>5481</td>
<td>Tre-Hold Sprout Inhibitor A112</td>
<td>Ethyl 1-naphthaleneacetate.</td>
</tr>
<tr>
<td>CA990022</td>
<td>352</td>
<td>Dupont Asana XL Insecticide</td>
<td>Esfenvalerate.</td>
</tr>
<tr>
<td>FL030004</td>
<td>100</td>
<td>Fulfill</td>
<td>Pyrethrin.</td>
</tr>
<tr>
<td>FL040006</td>
<td>100</td>
<td>Fulfill Insecticide</td>
<td>Pyrethrin.</td>
</tr>
<tr>
<td>FL930010</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>GA110002</td>
<td>100</td>
<td>Ridomil Gold SL</td>
<td>Metalaxyl-M.</td>
</tr>
<tr>
<td>GA170003</td>
<td>352</td>
<td>Dupont Fexapan Herbicide</td>
<td>Dicamba, diglycolamine salt.</td>
</tr>
<tr>
<td>GA990005</td>
<td>5481</td>
<td>Vapam HL Soil Fumigant</td>
<td>Metam-sodium.</td>
</tr>
<tr>
<td>HI120004</td>
<td>100</td>
<td>Evik 80 WDG</td>
<td>Ametryn.</td>
</tr>
<tr>
<td>ID000010</td>
<td>100</td>
<td>Fulfill</td>
<td>Pyrethrin.</td>
</tr>
<tr>
<td>ID060007</td>
<td>241</td>
<td>Prowl H2O Herbicide</td>
<td>Pendimethalin.</td>
</tr>
<tr>
<td>ID080006</td>
<td>66330</td>
<td>Etox 480 SC Fungicide</td>
<td>Fluoxastrobin.</td>
</tr>
<tr>
<td>ID090016</td>
<td>5481</td>
<td>Orthene 97</td>
<td>Acephate.</td>
</tr>
<tr>
<td>ID110005</td>
<td>59639</td>
<td>Metconazole 50 WDG Fungicide</td>
<td>Metconazole.</td>
</tr>
<tr>
<td>ID960008</td>
<td>7969</td>
<td>Basagran Herbicide</td>
<td>Sodium bentazon.</td>
</tr>
<tr>
<td>IN110002</td>
<td>100</td>
<td>Ridomil Gold SL</td>
<td>Metalaxyl-M.</td>
</tr>
<tr>
<td>KY140038</td>
<td>100</td>
<td>Ridomil Gold SL</td>
<td>Metalaxyl-M.</td>
</tr>
<tr>
<td>LA070001</td>
<td>241</td>
<td>Scepter 70 DG Herbicide</td>
<td>Imazaquin.</td>
</tr>
<tr>
<td>LA120001</td>
<td>352</td>
<td>Dupont Dermacor X–100 Seed Treatment</td>
<td>Chlorantraniliprole.</td>
</tr>
<tr>
<td>LA120016</td>
<td>241</td>
<td>Prowl H2O Herbicide</td>
<td>Pendimethalin.</td>
</tr>
<tr>
<td>LA140002</td>
<td>8033</td>
<td>Intruder Brand Insecticide</td>
<td>Acetamiprid.</td>
</tr>
<tr>
<td>LA950005</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>ME100001</td>
<td>50534</td>
<td>Bravo ZN</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>MI040001</td>
<td>50534</td>
<td>Bravo 720</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>MI040002</td>
<td>50534</td>
<td>Bravo ZN</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>MI100002</td>
<td>50534</td>
<td>Bravo Weather Stik</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>MI120001</td>
<td>50534</td>
<td>Bravo 720</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>MI130004</td>
<td>100</td>
<td>Cannonball WP</td>
<td>Fludioxonil.</td>
</tr>
<tr>
<td>MN030006</td>
<td>50534</td>
<td>Bravo WeatherStik</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>MN030007</td>
<td>50534</td>
<td>Bravo Ultrex</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>MN030008</td>
<td>50534</td>
<td>Bravo ZN</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>MN080002</td>
<td>66330</td>
<td>Malathion 5 EC</td>
<td>Malathion.</td>
</tr>
<tr>
<td>MO030005</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>MO130001</td>
<td>352</td>
<td>Dupont Realm Q Herbicide</td>
<td>Mesotrione; Rimsulfuron.</td>
</tr>
<tr>
<td>MO930007</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>MO940005</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>MS090007</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>MT030008</td>
<td>100</td>
<td>Fulfill</td>
<td>Pyrethrin.</td>
</tr>
<tr>
<td>Registration No.</td>
<td>Company No.</td>
<td>Product name</td>
<td>Chemical name</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------</td>
<td>--------------</td>
<td>---------------</td>
</tr>
<tr>
<td>MT080003</td>
<td>39039</td>
<td>Python Insecticide Cattle Ear Tag</td>
<td>Piperonyl butoxide; Zeta-Cypermethrin.</td>
</tr>
<tr>
<td>MT110001</td>
<td>59639</td>
<td>Metconazole 50 WDG Fungicide</td>
<td>Metconazole.</td>
</tr>
<tr>
<td>MT960001</td>
<td>7969</td>
<td>Basagran Herbicide</td>
<td>Sodium bentazon.</td>
</tr>
<tr>
<td>NC070003</td>
<td>59639</td>
<td>Select Max Herbicide in Inside Technology</td>
<td>Clethodim.</td>
</tr>
<tr>
<td>NC110004</td>
<td>100</td>
<td>Ridomil Gold SL</td>
<td>Metalaxyl-M.</td>
</tr>
<tr>
<td>NC120001</td>
<td>241</td>
<td>Prowl H2O Herbicide</td>
<td>Pendimethalin.</td>
</tr>
<tr>
<td>NC130003</td>
<td>5481</td>
<td>Vapam HL Soil Fumigant</td>
<td>Metalaxyl-m.</td>
</tr>
<tr>
<td>NC830009</td>
<td>5481</td>
<td>Zeneca Vapam 4-S Soil Fumigant Solution</td>
<td>Metalaxyl-m.</td>
</tr>
<tr>
<td>ND030007</td>
<td>50534</td>
<td>Bravo Weatherstik</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>ND030008</td>
<td>50534</td>
<td>Bravo ZN</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>ND170007</td>
<td>70506</td>
<td>Super Tin 4L</td>
<td>Fentin hydroxide.</td>
</tr>
<tr>
<td>NE090001</td>
<td>50534</td>
<td>Bravo 720</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>NE090002</td>
<td>50534</td>
<td>Bravo ZN</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>NJ110001</td>
<td>50534</td>
<td>Bravo 720</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>NM140002</td>
<td>34704</td>
<td>Malathion 8 Aquamul</td>
<td>Malathion.</td>
</tr>
<tr>
<td>NV000004</td>
<td>100</td>
<td>Fulfill</td>
<td>Pyrimethamine.</td>
</tr>
<tr>
<td>NV110002</td>
<td>59639</td>
<td>Valor Herbicide</td>
<td>Flumioxazin.</td>
</tr>
<tr>
<td>NY120001</td>
<td>7969</td>
<td>Headline Fungicide</td>
<td>Pyraclostrobin.</td>
</tr>
<tr>
<td>NY120012</td>
<td>7969</td>
<td>Bas 556 SC</td>
<td>Pyraclostrobin; Metconazole.</td>
</tr>
<tr>
<td>NY120013</td>
<td>7969</td>
<td>Headline SC</td>
<td>Pyraclostrobin.</td>
</tr>
<tr>
<td>NY140004</td>
<td>7969</td>
<td>Mervion Xemium Brand Fungicide</td>
<td>Pyraclostrobin; Flupyradroxyl.</td>
</tr>
<tr>
<td>NY140005</td>
<td>7969</td>
<td>Priaxon Xemium Brand Fungicide</td>
<td>Pyraclostrobin; Flupyradroxyl.</td>
</tr>
<tr>
<td>NY170003</td>
<td>352</td>
<td>Dupont Fexapan Herbicide</td>
<td>Dicamba, diglycolamine salt.</td>
</tr>
<tr>
<td>OH110005</td>
<td>100</td>
<td>Ridomil Gold SL</td>
<td>Metalaxyl-M.</td>
</tr>
<tr>
<td>OK090002</td>
<td>39039</td>
<td>Python Insecticide Cattle Ear Tag</td>
<td>Piperonyl butoxide; Zeta-Cypermethrin.</td>
</tr>
<tr>
<td>OR040004</td>
<td>100</td>
<td>Fulfill</td>
<td>Pyrimethamine.</td>
</tr>
<tr>
<td>OR040005</td>
<td>100</td>
<td>Fulfill</td>
<td>Pyrimethamine.</td>
</tr>
<tr>
<td>OR070018</td>
<td>66222</td>
<td>Diazinon AG500</td>
<td>Diazinon.</td>
</tr>
<tr>
<td>OR110004</td>
<td>7969</td>
<td>Basf Poast Herbicide</td>
<td>Sethoxydim.</td>
</tr>
<tr>
<td>OR950033</td>
<td>7969</td>
<td>Basagran Herbicide</td>
<td>Sodium bentazon.</td>
</tr>
<tr>
<td>OR990003</td>
<td>100</td>
<td>Bravo 825</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>OR990004</td>
<td>100</td>
<td>Bravo 720</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>SC120001</td>
<td>100</td>
<td>Ridomil Gold SL</td>
<td>Metalaxyl-M.</td>
</tr>
<tr>
<td>SC960006</td>
<td>5481</td>
<td>Vapam HL Soil Fumigant</td>
<td>Metam-sodium.</td>
</tr>
<tr>
<td>SD110003</td>
<td>39039</td>
<td>Python Insecticide Cattle Ear Tag</td>
<td>Piperonyl butoxide; Zeta-Cypermethrin.</td>
</tr>
<tr>
<td>SD120001</td>
<td>7969</td>
<td>Optifl Pro Powered by Kixor Herbicide</td>
<td>Imazethapyr; Saflufenacil.</td>
</tr>
<tr>
<td>TN050001</td>
<td>5481</td>
<td>Orthene 97</td>
<td>Acephate.</td>
</tr>
<tr>
<td>TN110002</td>
<td>100</td>
<td>Ridomil Gold SL</td>
<td>Metalaxyl-M.</td>
</tr>
<tr>
<td>TN130008</td>
<td>34704</td>
<td>Tombstone</td>
<td>Cyfluthrin.</td>
</tr>
<tr>
<td>TX930007</td>
<td>59639</td>
<td>Cobra Herbicide</td>
<td>Lactofen.</td>
</tr>
<tr>
<td>TX930002</td>
<td>59639</td>
<td>Valen Bolero 8 EC</td>
<td>Thiobencarb.</td>
</tr>
<tr>
<td>TX980004</td>
<td>5481</td>
<td>Orthene Turf, Tree &amp; Ornamental Spray B WSP</td>
<td>Acephate.</td>
</tr>
<tr>
<td>UT000010</td>
<td>100</td>
<td>Fulfill</td>
<td>Pyrimethamine.</td>
</tr>
<tr>
<td>UT090001</td>
<td>8033</td>
<td>Assail 70WP Insecticide</td>
<td>Acetamiprid.</td>
</tr>
<tr>
<td>UT120003</td>
<td>100</td>
<td>Gramoxone SL 2.0</td>
<td>Paraquat dichloride.</td>
</tr>
<tr>
<td>UT990004</td>
<td>352</td>
<td>Vyrdate L Insecticide/Nematicide</td>
<td>Oxamyl.</td>
</tr>
<tr>
<td>UT990005</td>
<td>5481</td>
<td>Dibrom 8 Emulsive</td>
<td>Naled.</td>
</tr>
<tr>
<td>VA050004</td>
<td>70506</td>
<td>Waylay 3.2 AG Permethrin Insecticide</td>
<td>Permethrin.</td>
</tr>
<tr>
<td>VA110002</td>
<td>100</td>
<td>Ridomil Gold SL</td>
<td>Metalaxyl-M.</td>
</tr>
<tr>
<td>WA000016</td>
<td>100</td>
<td>Fulfill</td>
<td>Pyrimethamine.</td>
</tr>
<tr>
<td>WA000017</td>
<td>100</td>
<td>Fulfill</td>
<td>Pyrimethamine.</td>
</tr>
<tr>
<td>WA110004</td>
<td>66330</td>
<td>ARY 0454-105 Suspension Concentrate Herbicide</td>
<td>Flucarbazone-sodium.</td>
</tr>
<tr>
<td>WA120011</td>
<td>59639</td>
<td>Valor Herbicide</td>
<td>Flumioxazin.</td>
</tr>
<tr>
<td>WA130007</td>
<td>100</td>
<td>Fusilade II Turf and Ornamental Herbicide</td>
<td>Fluzifop-P-butyl.</td>
</tr>
<tr>
<td>WA900005</td>
<td>34704</td>
<td>Clean Crop Simazine 4L Flowable Herbicide</td>
<td>Simazine.</td>
</tr>
<tr>
<td>WA900012</td>
<td>7969</td>
<td>Basagran</td>
<td>Sodium bentazon.</td>
</tr>
<tr>
<td>WI130009</td>
<td>50534</td>
<td>Bravo 825 Agricultural Fungicide</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>WI130010</td>
<td>50534</td>
<td>Bravo 720</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>WI130011</td>
<td>50534</td>
<td>Bravo ZN</td>
<td>Chlorothalonil.</td>
</tr>
<tr>
<td>WI130013</td>
<td>50534</td>
<td>Bravo 720</td>
<td>Chlorothalonil.</td>
</tr>
</tbody>
</table>

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in this unit.
TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

<table>
<thead>
<tr>
<th>EPA Company No.</th>
<th>Company name and address</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 .............</td>
<td>Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419.</td>
</tr>
<tr>
<td>228 .............</td>
<td>Nufarm Americas, Inc., 4020 Aerial Center Parkway, Suite 101, Morrisville, NC 27560.</td>
</tr>
<tr>
<td>241 .............</td>
<td>BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709.</td>
</tr>
<tr>
<td>264 .............</td>
<td>Bayer Cropscience LP, P.O. Box 12014, Research Triangle Park, NC 27709.</td>
</tr>
<tr>
<td>270 .............</td>
<td>Farnam Companies, Inc., 1501 E Woodfield Road, Suite 200 West, Schaumburg, IL 60173.</td>
</tr>
<tr>
<td>352 .............</td>
<td>E. I. Du Pont de Nemours and Company, Chestnut Run Plaza, 974 Centre Road, Wilmington, DE 19805.</td>
</tr>
<tr>
<td>400 .............</td>
<td>Macdermich Agricultural Solutions, Inc., c/o Arysta Lifesciences North America, LLC, 15401 Weston Parkway, Suite 150, Cary, NC 27513.</td>
</tr>
<tr>
<td>432 .............</td>
<td>Bayer Environmental Science, A Division of Bayer Cropscience LP, P.O. Box 12014, Research Triangle Park, NC 27709.</td>
</tr>
<tr>
<td>875 .............</td>
<td>Diversey, Inc., 1410 Newman Road, Racine, WI 53406.</td>
</tr>
<tr>
<td>2596 ..........</td>
<td>The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094.</td>
</tr>
<tr>
<td>2724 ..........</td>
<td>Wellmark International, 1501 E Woodfield Road, Suite 200 West, Schaumburg, IL 60173.</td>
</tr>
<tr>
<td>3862 ..........</td>
<td>ABC Compound Co., Inc., P.O. Box 60729, Coventry, GA 30013.</td>
</tr>
<tr>
<td>5383 ..........</td>
<td>Troy Chemical Corp., c/o Troy Corporation, 8 Vreeland Road, Florham Park, NJ 07932.</td>
</tr>
<tr>
<td>5481 ..........</td>
<td>AMVAC Chemical Corporation, 4695 MacArthur Court, Suite 1200, Newport Beach, CA 92660.</td>
</tr>
<tr>
<td>5736 ..........</td>
<td>Diversey, Inc., 1410 Newman Road, Racine, WI 53406.</td>
</tr>
<tr>
<td>5813 ..........</td>
<td>The Clorox Co., c/o PS&amp;RC, P.O. Box 493, Pleasanton, CA 94566.</td>
</tr>
<tr>
<td>7173 ..........</td>
<td>Liphatech, Inc., 3600 W Elm Street, Milwaukee, WI 53209.</td>
</tr>
<tr>
<td>7969 ..........</td>
<td>BASF Corporation, Agricultural Products, P.O. Box 13528, Research Triangle Park, NC 27709.</td>
</tr>
<tr>
<td>9198 ..........</td>
<td>The Andersons, Inc., P.O. Box 119, Maumee, OH 43537.</td>
</tr>
<tr>
<td>10163 ..........</td>
<td>Gowen Company, P.O. Box 5569, Yuma, AZ 85366.</td>
</tr>
<tr>
<td>11556 ..........</td>
<td>Bayer Healthcare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.</td>
</tr>
<tr>
<td>28293 ..........</td>
<td>Pheaton Corp., d/b/a Unicorn Laboratories, 1501 E Woodfield Road, Suite 200 West, Schaumburg, IL 60173.</td>
</tr>
<tr>
<td>34704 ..........</td>
<td>Loveland Products, Inc., P.O. Box 1286, Greeley, CO 80632.</td>
</tr>
<tr>
<td>39039 ..........</td>
<td>Y-Tex Corporation, 1825 Big Horn Avenue, Cody, WY 82414.</td>
</tr>
<tr>
<td>50534 ..........</td>
<td>GB Biosciences, LLC, P.O. Box 18300, Greensboro, NC 27419.</td>
</tr>
<tr>
<td>53883 ..........</td>
<td>Control Solutions, Inc., 5903 Genoa Red Bluff Road, Pasadena, TX 77507.</td>
</tr>
<tr>
<td>59639 ..........</td>
<td>Valent U.S.A. Corporation, 1600 Riviera Avenue, Suite 200, Walnut Creek, CA 94596.</td>
</tr>
<tr>
<td>67619 ..........</td>
<td>Clorox Professional Products Company, c/o PS&amp;RC, P.O. Box 493, Pleasanton, CA 94566.</td>
</tr>
<tr>
<td>68156 ..........</td>
<td>Dintec Agrichemicals, LLC, 3122 Zionsville Road, Indianapolis, IN 46268.</td>
</tr>
<tr>
<td>69961 ..........</td>
<td>Alchem Performance Products, 6010 NW First Place, Gainesville, FL 32607.</td>
</tr>
<tr>
<td>70927 ..........</td>
<td>Diversey, Inc., 1410 Newman Road, Racine, WI 53406.</td>
</tr>
<tr>
<td>85588 ..........</td>
<td>DuPont Crop Protection, Agent for Agsurf Corporation, Chestnut Run Plaza, 974 Center Road, Newark, DE 19805.</td>
</tr>
</tbody>
</table>

III. What is the Agency’s authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the Federal Register. EPA will provide a 30-day comment period on the proposed requests. Thereafter, the EPA Administrator may approve such a request.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation should submit such withdrawal in writing to the person listed under FOR FURTHER INFORMATION CONTACT. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Because the Agency has identified no significant potential risk concerns associated with these pesticide products, upon cancellation of the products identified in Table 1 of Unit II., EPA anticipates allowing registrants to sell and distribute existing stocks of these products until January 15, 2019, or the date of that the cancellation notice is published in the Federal Register, whichever is later. Thereafter, registrants will be prohibited from selling or distributing the pesticides identified in Table 1 of Unit II., except for export consistent with FIFRA section 17 or for proper disposal. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

Authority: 7 U.S.C. 136 et seq.
ENVIRONMENTAL PROTECTION AGENCY

[9982–45–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Georgia

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA’s approval of the State of Georgia’s request to revise its National Primary Drinking Water Regulations Implementation EPA-authorized program to allow electronic reporting.

DATES: EPA approves the authorized program revision for the State of Georgia’s National Primary Drinking Water Regulations Implementation as of November 19, 2018, if no timely request for a public hearing is received and accepted by the Agency.

FOR FURTHER INFORMATION CONTACT: Devon Martin, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2824T, 1200 Pennsylvania Avenue NW, Washington, DC 20460, (202) 566–2603, martin.devon@epa.gov.

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the Federal Register (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On August 8, 2018, the Georgia Department of Natural Resources (GA DNR) submitted an application titled “Electronic Sample Entry Verify” for revision to its EPA-approved drinking water program under title 40 CFR to allow new electronic reporting. EPA reviewed GA DNR’s request to revise its EPA-authorized program and, based on this review, EPA determined that the application met the standards for approval of authorized program revision set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA’s decision to approve Georgia’s request to revise its Part 142—National Primary Drinking Water Regulations Implementation program to allow electronic reporting under 40 CFR part 141 is being published in the Federal Register.

GA DNR was notified of EPA’s determination to approve its application with respect to the authorized program listed above.

Also, in today’s notice, EPA is informing interested persons that they may request a public hearing on EPA’s action to approve the State of Georgia’s request to revise its authorized National Primary Drinking Water Regulations Implementation program under 40 CFR part 142, in accordance with 40 CFR 3.1000(f), to allow for electronic reporting. Requests for a hearing must be submitted to EPA within 30 days of publication of today’s Federal Register notice. Such requests should include the following information:

(1) The name, address and telephone number of the individual, organization or other entity requesting a hearing;

(2) A brief statement of the requesting person’s interest in EPA’s determination, a brief explanation as to why EPA should hold a hearing, and any other information that the requesting person wants EPA to consider when determining whether to grant the request;

(3) The signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

In the event a hearing is requested and granted, EPA will provide notice of the hearing in the Federal Register not less than 15 days prior to the scheduled hearing date. Frivolous or insubstantial requests for hearing may be denied by EPA. Following such a public hearing, EPA will review the record of the hearing and issue an order either affirming today’s determination or rescinding such determination. If no timely request for a hearing is received and granted, EPA’s approval of the State of Georgia’s request to revise its part 142—National Primary Drinking Water Regulations Implementation program to allow electronic reporting will become effective 30 days after today’s notice is published, pursuant to CROMERR section 3.1000(f)(4).

Matthew Leonard,
Director, Office of Information Management.

[FR Doc. 2018–22860 Filed 10–18–18; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY


Proposed Information Collection Request; Comment Request; Fuel Use Requirements for Great Lake Steamships; Renewal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), “Fuel Use Requirements for Great Lakes Steamships” (EPA ICR No. 2458.03, OMB Control No. 2060–0679) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through October 31, 2018. Public comments were previously requested via the Federal Register on June 15, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An Agency may not conduct or sponsor a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.
DATES: Additional comments may be submitted on or before November 19, 2018.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OLEM–2018–0391, to (1) EPA, either online using www.regulations.gov (our preferred method), or by email to: EPA Docket Center, Environmental Protection Agency, Mail Code 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460, and (2) OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA’s policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Alan Stout, Office of Transportation and Air Quality, Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105; 734–214–4805; stout.alan@epa.gov.

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA’s public docket, visit http://www.epa.gov/dockets.

Abstract: The U.S. Environmental Protection Agency (EPA) adopted requirements for marine vessels operating in and around U.S. territorial waters to use reduced-sulfur diesel fuel. This requirement does not apply for steamships, but it would apply for steamships that are converted to run on diesel engines. A regulatory provision allows vessel owners to qualify for a waiver from the fuel-use requirements for a defined period for such converted vessels. One condition of the exemption from the fuel standard is that engines meet current emission standards. EPA uses the data to oversee compliance with regulatory requirements, including communicating with affected companies and answering questions from the public or other industry participants regarding the waiver in question. Since the IMO Tier III NOX standards apply for Category 3 engines installed on U.S. vessels, we don’t expect anyone to use the steamship exemption.

ENVIRONMENTAL PROTECTION AGENCY

[FR Doc. 2018–22808 Filed 10–18–18; 8:45 am]

BILLING CODE 6560–50–P

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Facility Ground-Water Monitoring Requirements (EPA ICR Number 0959.16, OMB Control Number 2050–0033), to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through October 31, 2018. Public comments were previously requested via the Federal Register on July 3, 2018 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before November 19, 2018.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OLEM–2018–0391, to (1) EPA, either online using www.regulations.gov (our preferred method), or by email to rcra-docket@epa.gov, or by mail to: RCRA Docket (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; and (2) OMB via email to oira_submission@omb.eop.gov. Address comments to OMB Desk Officer for EPA.

EPA’s policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Peggy Vyas, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 703–308–5477; fax number: 703–308–8433; email address: vyas.peggy@epa.gov.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA’s public docket, visit http://www.epa.gov/dockets.

Abstract: Subtitle C of the Resource Conservation and Recovery Act (RCRA) creates a comprehensive program for the safe management of hazardous waste. Section 3004 of RCRA requires owners and operators of facilities that treat, store, or dispose of hazardous waste to comply with standards established by EPA that are to protect the environment. Section 3005 provides for implementation of these standards under permits issued to owners and operators by EPA or authorized States. Section 3005 also allows owners and operators of facilities in existence when the regulations came into effect to comply with applicable notice requirements to operate until a permit is issued or denied. This statutory authorization to operate prior to permit determination is commonly known as “interim status.” Owners and operators of interim status facilities also must comply with standards set under Section 3004.
NOTICE OF INTENT TO TERMINATE RECEIVERSHIP

<table>
<thead>
<tr>
<th>Fund</th>
<th>Receivership name</th>
<th>City</th>
<th>State</th>
<th>Date of appointment of receiver</th>
</tr>
</thead>
<tbody>
<tr>
<td>10142</td>
<td>Madisonville State Bank</td>
<td>Madisonville</td>
<td>TX</td>
<td>10/30/2009</td>
</tr>
</tbody>
</table>

The liquidation of the assets for the receivership has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing, identify the receivership to which the comment pertains, and sent within thirty days of the date this notice appears to: Federal Deposit Insurance Corporation, Executive Secretary. [FR Doc. 2018–22814 Filed 10–18–18; 8:45 am]

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary by email at Secretary@fmc.gov, or by mail, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the Federal Register. Copies of agreements are available through the Commission’s website (www.fmc.gov) or by contacting the Office of Agreements at (202) 523–5793 or tradeanalysis@ fmc.gov.

Agreement No.: 201279.

Agreement Name: Concession Agreement between Diamond State Port Corporation and GT USA Wilmington, LLC.

Parties: Diamond State Port Corporation and GT USA Wilmington, LLC.

Filing Party: Elizabeth Lowe; Venable LLP.

Synopsis: The amendment adds the Caribbean Coast of Colombia to the geographic scope of the Agreement.

Proposed Effective Date: 10/12/2018.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1891.

Notice is hereby given that the Federal Deposit Insurance Corporation (FDIC or Receiver) as Receiver for the institution listed below intends to terminate its receivership for said institution.
Mexico to the geographic scope of the Agreement.

Proposed Effective Date: 10/12/2018.
Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1879.

Agreement No.: 201280.
Agreement Name: BBC/Seaboard Vessel Sharing Agreement.

Parties: BBC Chartering & Logistics GmbH & Co. KG, BBC Chartering Carriers GmbH & Co KG, and BBC Project Chartering GmbH Co KG (acting as a single party); and Seaboard Marine Ltd.

Filing Party: Wayne Rohde; Cozen O’Connor.

Synopsis: The Agreement authorizes the parties to share vessels in the trade between the U.S. Gulf Coast and ports in Jamaica, the Dominican Republic, Chile, Peru, Ecuador, and on the Gulf Coast of Mexico.

Proposed Effective Date: 11/29/2018.
Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/19300.

Rachel Dickon,
Secretary.

[B] [R] [F] Doc. 2018-22819 Filed 10–18–18; 8:45 am

BILLING CODE 6731–AA–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Public Comment Request; Independent Living Services Program Performance Report (0985–0043)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This proposed Extension with Changes of a Currently Approved Collection (ICR Rev) solicits comments on the information collection requirements relating to the Independent Living Services (ILS) program under the Rehabilitation Act of 1973, 29 U.S.C. 701, et seq.

DATES: Comments on the information collection request must be submitted electronically by 11:59 p.m. (EST) or postmarked by December 18, 2018.

ADDRESSES: Submit electronic comments on the information collection request to: Peter Nye at peter.nye@acl.hhs.gov. Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Peter Nye.

FOR FURTHER INFORMATION CONTACT: Peter Nye, Administration for Community Living, Washington, DC 20201, (202) 795–7606 or peter.nye@acl.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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL’s functions, including whether the information will have practical utility;

(2) the accuracy of ACL’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(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.

In the context of ACL, IL programs are supported through funding authorized by the Rehabilitation Act of 1973, as amended (The Act). Title VII, chapter 1 of the Act states the current purpose of the program is to “promote a philosophy of independent living including a philosophy of consumer control, peer support, self-help, self-determination, equal access, and individual and system advocacy, in order to maximize the leadership, empowerment, independence, and productivity of individuals with disabilities, and the integration and full inclusion of individuals with disabilities into the mainstream of American society.”

The IL program provides financial assistance, through formula grants, to states, the District of Columbia, Puerto Rico, and outlying areas for providing, expanding, and improving the provision of IL services. The Designated State Entity (DSE) is the agency that, on behalf of the state, receives, accounts for, and disburses funds received under Subchapter B of the Act. Funds are also made available for the provisions of training and technical assistance to SILCs.

The Act of 1973 requires three IL program reports: (1) State Plan for Independent Living, (2) ILS PPR, and (3) Centers for Independent Living PPR. The ILS PPR and CIL PPR were previously combined into one submission. However, for the purposes of this data collection, the ILS PPR and CIL PPR are being submitted separately because they are separate collections of different information from different parties. Separating these PRA processes reduces confusion and increases the Independent Living Administration’s ability to identify issues specific to DSEs and SILCs. This request is for the ILS PPR, which is submitted annually by the Statewide Independent Living Council and DSE in every state that receives Subchapter B funds. The ILS PPRs are used by ACL to assess grantees’ compliance with title VII of the Act, with 45 CFR part 349 of the Code of Federal Regulations, and with applicable provisions of the HHS Regulations at 45 CFR part 75. The ILS PPR serves as the primary basis for ACL’s monitoring activities in fulfillment of its responsibilities under sections 706 and 722 of the Act. The PPR is also used by ACL to design CIL and SILC training and technical assistance programs authorized by section 721 of the Act.

The current version of the ILS PPR that ILS is requesting an extension for was approved by OMB, but will expire on December 31, 2018. ILS plans to
The Independent Living (SPIL) (0985–0044) is soliciting comments on the information collection to: Peter Nye at peter.nye@acl.hhs.gov. Submit written comments on the collection of information to: Peter Nye, Administration for Community Living, Washington, DC 20201, Attention: Peter Nye.

FOR FURTHER INFORMATION CONTACT: Peter Nye, Administration for Community Living, Washington, DC 20201, (202) 795–7606, or peter.nye@acl.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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This Extension Without Changes (Information Collection Request Ext) solicits comments on the information collection requirements related to the State Plan for Independent Living (SPIL) required under the Rehabilitation Act of 1973, as amended. The Independent Living Administration within ACL is proposing to extend the currently approved forms for one year while we work on a revision. However, we expect to complete the redesign of the proposed information collection forms well before the expiration of the extension.

<table>
<thead>
<tr>
<th>Respondent/data collection activity</th>
<th>Number of respondents</th>
<th>Responses per respondent</th>
<th>Hours per response</th>
<th>Annual burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>SILCs and DSEs</td>
<td>56</td>
<td>1 (for each SILC and DSE combined)</td>
<td>35</td>
<td>1,960</td>
</tr>
<tr>
<td>Total</td>
<td>56</td>
<td>1</td>
<td>35</td>
<td>1,960</td>
</tr>
</tbody>
</table>

Dated: October 9, 2018.

Mary Lazare,
Principal Deputy Administrator.

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Public Comment Request; the State Plan for Independent Living (SPIL) (0985–0044)

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This Extension Without Changes (Information Collection Request Ext) solicits comments on the information collection requirements related to the State Plan for Independent Living (SPIL) required under the Rehabilitation Act of 1973, as amended. The Independent Living Administration within ACL is proposing to extend the currently approved forms for one year while we work on a revision. However, we expect to complete the redesign of the proposed information collection forms well before the expiration of the extension.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by December 18, 2018.

ADDRESSES: Submit electronic comments on the collection of information to: Peter Nye at peter.nye@acl.hhs.gov. Submit written comments on the collection of information to: Peter Nye, Administration for Community Living, Washington, DC 20201, Attention: Peter Nye.

FOR FURTHER INFORMATION CONTACT: Peter Nye, Administration for Community Living, Washington, DC 20201, (202) 795–7606, or peter.nye@acl.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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

1. Whether the proposed collection of information is necessary for the proper performance of ACL’s functions, including whether the information will have practical utility;
2. the accuracy of ACL’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;
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.

Legal authority for the State Plan for Independent Living is contained in Chapter 1 of Title VII of the Rehabilitation Act of 1973, as amended by the Workforce Innovation and Opportunity Act (Pub. L. 113–128). Section 704 of the Rehabilitation Act requires that, to be eligible to receive financial assistance under Chapter 1, “a State shall submit to the Department, and obtain approval of, a State plan containing such provisions as the Department may require.” The Administration for Community Living’s (ACL) approval of the SPIL is required for states to receive federal funding for both the Independent Living Services State grants and Centers for Independent Living programs. Federal statute and regulations require the collection of this information every three years. The current three-year approval period for the SPIL expires April 30, 2019.

The SPIL is jointly developed by the chairperson of the Statewide Independent Living Council and the directors of the centers for independent living in the State, after receiving public input from individuals throughout the State; and signed by the chairperson of the Statewide Independent Living Council, acting on behalf of—and at the direction of—the Council, the director.
of the designated State entity, and not less than 51 percent of the directors of the centers for independent living in the State. ACL reviews the SPIL for compliance with the Rehabilitation Act and 45 CFR part 1329 and approves it. The SPIL also serves as a primary planning document for continuous monitoring of, and technical assistance to, the state independent living programs to ensure appropriate planning, financial support and coordination, and other assistance to appropriately address, on a statewide basis, needs for the provision of independent living services in the state. The proposed data collection tools may be found on the ACL website for review at https://www.acl.gov/about-acl/public-input.

**Estimated Program Burden:** ACL estimates the burden of this collection of information as follows: 56 Statewide Independent Living Councils will respond to the requirement for a SPIL every three years. It will take approximately 60 hours for each state’s Statewide Independent Living Council to jointly complete the development of the SPIL for a total of approximately 3,360 hours. This estimate is based on amounts of time that Statewide Independent Living Councils have reported that they have spent responding to previous requests for this report. ACL is not requesting any change in the data States are required to submit. As such, there is no change to the estimated reporting burden.

<table>
<thead>
<tr>
<th>Respondent/data collection activity</th>
<th>Number of respondents</th>
<th>Responses per respondent</th>
<th>Hours per response</th>
<th>Annual burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statewide Independent Living Councils</td>
<td>56</td>
<td>1</td>
<td>60</td>
<td>3,360</td>
</tr>
<tr>
<td>Total</td>
<td>56</td>
<td>1</td>
<td>60</td>
<td>3,360</td>
</tr>
</tbody>
</table>

Dated: October 10, 2018.

Mary Lazare,  
Principal Deputy Administrator.

[FR Doc. 2018–22753 Filed 10–18–18; 8:45 am]

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Community Living**

**Agency Information Collection Activities; Proposed Collection; Public Comment Request; Centers for Independent Living Program Performance Report (0985–NEW)**

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice.

This New Data Collection (ICR New) solicits comments on the information collection requirements relating to the Centers for Independent Living under the Rehabilitation Act of 1973.

**DATES:** Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by December 18, 2018.

**ADDRESSES:** Submit electronic comments on the collection of information to: Peter Nye at peter.nye@acl.hhs.gov. Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Peter Nye.

**FOR FURTHER INFORMATION CONTACT:** Peter Nye, Administration for Community Living, Washington, DC 20024, (202) 795–7606 or peter.nye@acl.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, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

1. Whether the proposed collection of information is necessary for the proper performance of ACL’s functions, including whether the information will have practical utility;

(2) the accuracy of ACL’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(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.

In the context of ACL, IL programs are supported through funding authorized by the Rehabilitation Act of 1973, as amended (The Act). Title VII, chapter 1 of the Act states the current purpose of the program is to “promote a philosophy of independent living including a philosophy of consumer control, peer support, self-help, self-determination, equal access, and individual and system advocacy, in order to maximize the leadership, empowerment, independence, and productivity of individuals with disabilities, and the integration and full inclusion of individuals with disabilities into the mainstream of American society.”

ILS PPR and CIL PPR are being submitted separately because they are separate collections of different information from different parties. Separating these PRA processes reduces confusion and increases the Independent Living Administration’s ability to identify issues specific to CILs. This request is for CIL PPR, which is submitted annually by all CILs receiving IL Subchapter C funds. The PPRs are used by ACL to assess grantees’ compliance with title VII of the Act, and with 45 CFR 1329 of the Code of Federal
Regulations and with applicable provisions of the HHS Regulations at 45 CFR part 75. The PPR serves as the primary basis for ACL’s monitoring activities in fulfillment of its responsibilities under sections 706 and 722 of the Act. The PPR also enables ACL to track performance outcomes and efficiency measures of the Centers for Independent Living (CIL) programs with respect to the annual and long-term performance targets established in compliance with GPRA. The PPR is also used by ACL to design CIL and SILC training and technical assistance programs authorized by section 711A and section 721 of the Act.

ACL published a Federal Register Notice regarding the independent living programs information collection on February 23, 2017. Two-hundred and twenty-one individual comments were received. The responses indicated a need to make substantial changes to the collection. The current version of the ILS PPR that ILA is requesting an extension for was approved by OMB, but will expire on December 31, 2018. Further deliberation is needed to ensure that we appropriately address all of the concerns. ILA is proposing to extend the currently approved forms for three years while we work on a revision that addresses all the suggested changes.

<table>
<thead>
<tr>
<th>Respondent/data collection activity</th>
<th>Number of respondents</th>
<th>Responses per respondent</th>
<th>Hours per response</th>
<th>Annual burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers for Independent Living</td>
<td>353</td>
<td>1</td>
<td>35</td>
<td>12,355</td>
</tr>
</tbody>
</table>

Dated: October 9, 2018.

Mary Lazare,  
Principal Deputy Administrator.

[FR Doc. 2016–22754 Filed 10–18–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1072]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Application for Participation in FDA Fellowship and Traineeship Programs.”

DATES: Submit either electronic or written comments on the collection of information by December 18, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 18, 2018. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 18, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2014–N–1072 for “Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper
submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law.

For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRASStaff@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, including each proposed extension of an existing 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.

Application for Participation in FDA Fellowship and Traineeship Programs

OMB Control Number 0910–0780—Revision

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code authorize Federal agencies to rate applicants for Federal jobs. The proposed information collection involves brief online applications completed by applicants applying to FDA’s Fellowship and Traineeship programs. These voluntary online applications will allow the Agency to easily and efficiently elicit and review information from students and healthcare professionals who are interested in becoming involved in FDA-wide activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with FDA.

FDA estimates the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commissioner’s Fellowship Program</td>
<td>600</td>
<td>1</td>
<td>600</td>
<td>1.33</td>
<td>798</td>
</tr>
<tr>
<td>Regulatory Science Internship Program</td>
<td>250</td>
<td>1</td>
<td>250</td>
<td>1</td>
<td>250</td>
</tr>
<tr>
<td>Medical Device Fellowship Program</td>
<td>250</td>
<td>1</td>
<td>250</td>
<td>1</td>
<td>250</td>
</tr>
<tr>
<td>FDA Traineeship Program</td>
<td>1000</td>
<td>1</td>
<td>1000</td>
<td>1</td>
<td>1000</td>
</tr>
<tr>
<td>Reagan-Udall Fellowship at FDA</td>
<td>50</td>
<td>1</td>
<td>50</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>2,348</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.

Because FDA is developing two new training programs, our estimated burden for the information collection reflects an overall increase of 1,050 hours and a corresponding increase of 1,050 responses/records. We attribute this adjustment to an increase in the number of submissions that we will receive with the new training programs.

Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Determination of Regulatory Review Period for Purposes of Patent Extension; IMFINZI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for IMFINZI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the SUPPLEMENTARY INFORMATION section) are incorrect may submit either electronic or written comments and ask for a redetermination by December 18, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 17, 2019. See “Petitions” in the SUPPLEMENTARY INFORMATION section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 17, 2019. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 17, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions
Submit electronic comments in the following way:
• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov. If you want to submit a comment with confidential personal information, you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:
• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
  • For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

  Instructions: All submissions received must include the Docket Nos. FDA–2017–E–6544 and FDA–2017–E–6542 for “Determination of Regulatory Review Period for Purposes of Patent Extension; IMFINZI.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.
• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with §10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory

Electronic Submissions
Submit electronic comments in the following way:
• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov. If you want to submit a comment with confidential personal information, you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:
• Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
  • For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

  Instructions: All submissions received must include the Docket Nos. FDA–2017–E–6544 and FDA–2017–E–6542 for “Determination of Regulatory Review Period for Purposes of Patent Extension; IMFINZI.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.
• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with §10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory
review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product IMFINZI (durvalumab). IMFINZI is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Subsequent to this approval, the USPTO received a patent term restoration application for IMFINZI (U.S. Patent Nos. 8,779,108 and 9,493,565) from MedImmune Limited, and the USPTO requested FDA’s assistance in determining the patents’ eligibility for patent term restoration. In a letter dated, January 9, 2018, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of IMFINZI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for IMFINZI is 1,755 days. Of this time, 1,554 days occurred during the testing phase of the regulatory review period, while 201 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective: July 13, 2012. FDA has verified the applicant’s claim that the date the initial investigational new drug application became effective was on July 13, 2012.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262): October 13, 2016. FDA has verified the applicant’s claim that the biologics license application (BLA) for IMFINZI (BLA 761069) was initially submitted on October 13, 2016.

3. The date the application was approved: May 1, 2017. FDA has verified the applicant’s claim that BLA 761069 was approved on May 1, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 159 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see DATES). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see DATES), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.
<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA 006002</td>
<td>Aralen Hydrochloride  (chloroquine hydrochloride (HCl)) Injection, Equivalent to (EQ) 40 milligram (mg) base/milliliter (mL); Aralen (chloroquine phosphate) Tablets, EQ 300 mg base.</td>
<td>Sanofi-Aventis, U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807.</td>
</tr>
<tr>
<td>NDA 008107</td>
<td>Leucovorin calcium for Injection USP, EQ 60 mg base/vial; for solution, oral; EQ 3 mg base/mL injection; EQ 50 mg base/vial injection; EQ 100 mg base/vial injection; EQ 350 mg base/vial injection.</td>
<td>Hospira Inc., Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017.</td>
</tr>
<tr>
<td>NDA 009321</td>
<td>Cholografin Meglumine (iodipamide meglumine) Injection, 10.3% and 52% (cholografin sodium, 20%).</td>
<td>Bracco Diagnostics, Inc., 259 Prospect Plains Rd., Monroe Township, NJ 08881.</td>
</tr>
<tr>
<td>NDA 017566</td>
<td>Brevicon (ethinyl estradiol; norethindrone) Tablets, 0.035 mg/0.5 mg (21-Day Regimen).</td>
<td>Allergan Pharmaceuticals International, Ltd., c/o Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612. Bayer HealthCare LLC, 100 Bayer Blvd., 100 Bayer Rd., Pittsburgh, PA 15205.</td>
</tr>
<tr>
<td>NDA 018181</td>
<td>Mycelex (clotrimazole) Topical Solution, 1%</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 018182</td>
<td>Mycelex-7 (clotrimazole) Tablets, 100 mg</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 018230</td>
<td>Mycelex-7 (clotrimazole) Topical Vaginal Cream, 1%</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 018856</td>
<td>D-Xylose (xylose) Powder, 25 grams (g)/bottle</td>
<td>Lyne Laboratories, 10 Burke Dr., Brockton, MA 02301.</td>
</tr>
<tr>
<td>NDA 018874</td>
<td>Calcijex (calcitriol) Injection, 0.001 mg/mL and 0.002 mg/mL</td>
<td>AbbVie, Inc., 1 North Waukegan Rd., North Chicago, IL 60064.</td>
</tr>
<tr>
<td>NDA 020214</td>
<td>Zemuron (rozomorn bromide) Injection, 50 mg/5 mL; 10 mg/mL; 10 mg/mL; 100 mg/10 mL (10 mg/mL).</td>
<td>Organon USA Inc., Subsidiary of Merck &amp; Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.</td>
</tr>
<tr>
<td>NDA 020389</td>
<td>Mycelex-7 Combination Pack (clotrimazole) Topical Vaginal Cream and Tablets, 1%, 100 mg.</td>
<td>Bayer HealthCare LLC.</td>
</tr>
<tr>
<td>NDA 020528</td>
<td>Mavik (trandolapril) Tablets, 1 mg, 2 mg, and 4 mg.</td>
<td>AbbVie, Inc.</td>
</tr>
<tr>
<td>NDA 020738</td>
<td>Teveten (eprrosartan mesylate) Tablets, 300 mg, 400 mg, and 600 mg.</td>
<td>Do.</td>
</tr>
<tr>
<td>NDA 021268</td>
<td>Teveten HCT (eprrosartan mesylate and hydrochlorothiazide) Tablets, 600/12.5 mg and 600/25 mg.</td>
<td>AbbVie, Inc.</td>
</tr>
<tr>
<td>NDA 021410</td>
<td>Avandamet (rosiglitazone maleate and metformin hydrochloride (HCl)) Tablets, 500 mg EQ 1 mg base; 500 mg EQ 2 mg base; 500 mg EQ 4 mg base; 1 g EQ 2 mg base; 1 g EQ 4 mg base.</td>
<td>GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426.</td>
</tr>
<tr>
<td>NDA 021511</td>
<td>Copegus (ribavirin) Tablets, 200 mg and 400 mg</td>
<td>Hoffmann La-Roche, Inc., Subsidiary of Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080.</td>
</tr>
<tr>
<td>NDA 021700</td>
<td>Avandaryl (glimepiride and rosiglitazone maleate) Tablets, 1 mg/4 mg; 2 mg/4 mg; 2 mg/8 mg; 4 mg/4 mg; 4 mg/8 mg.</td>
<td>SB Pharmco Puerto Rico Inc., Subsidiary of GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426.</td>
</tr>
</tbody>
</table>

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 19, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on November 19, 2018 may continue to be dispensed or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.


Leslie Kux, Associate Commissioner for Policy.
Using Stem Cells to Better Understand Heart Failure.

**Date:** November 2, 2018.

**Time:** 8:00 a.m. to 4:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hilton Crystal City Hilton Crystal City, 2309 Jefferson Davis Hwy., Arlington, VA 22202.

**Contact Person:** David A. Wilson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7204, Bethesda, MD 20892–7924, 301–435–0299, wilsonda2@nhlbi.nih.gov.

**Name of Committee:** National Heart, Lung, and Blood Institute Special Emphasis Panel; Bold New Bioengineering Methods and Approaches for Heart, Lung, Blood and Sleep Disorders and Diseases (R21).

**Date:** November 2, 2018.

**Time:** 8:00 a.m. to 5:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Westin Grand, 2350 M Street NW, Washington, DC 20037.

**Contact Person:** Susan Wolher Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, susan.sunnarborg@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

**Dated:** October 15, 2018.

Ronald J. Livingston, Jr., Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–22760 Filed 10–18–18; 8:45 am]

**BILLING CODE 4140–01–P**

---

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

[Docket No. USCG–2018–0877]

**National Maritime Security Advisory Committee; Meeting**

**AGENCY:** U.S. Coast Guard, Department of Homeland Security.

**ACTION:** Notice of Federal Advisory Committee meeting.

**SUMMARY:** The National Maritime Security Advisory Committee will meet in Houston, Texas, to review and discuss various issues relating to national maritime security. All meetings will be open to the public.

**DATES:** Meetings. The Committee will meet on Tuesday, November 6, 2018, from 12:00 noon to 5 p.m. and on Wednesday, November 7, 2018, from 8 a.m. to 1 p.m. These meetings may close early if all business is finished.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is in compliance with the Federal Advisory Committee Act, Title 5, United States Code, Appendix. The National Maritime Security Advisory Committee operates under the authority of 46 U.S.C. 70112.

The National Maritime Security Advisory Committee provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Commandant of the Coast Guard, on matters relating to national maritime security.

**Agenda**

**Day 1**

The Committee will meet to review, discuss and formulate recommendations on the following issues:

1. **Cyber Security Update.** Members will receive an update from the U.S. Coast Guard concerning the draft Cyber Security Navigation and Vessel Inspection Circular and other Cyber Security matters related to the Marine Transportation System.

2. **Unmanned Aircraft Systems.** The Committee will receive an update from the U.S. Coast Guard concerning the threat of Unmanned Aircraft Systems and the efforts of the U.S. Coast Guard to provide guidance to the maritime industry in addressing the concern these aircraft pose to critical infrastructure.

3. **Port of Houston Maritime Security Review.** The Committee will receive a brief on the current state of maritime security at the Port of Houston.

4. **Public Comment period.**

**Day 2**

The Committee will meet to review, discuss and formulate recommendations on the following issues:

1. **Member Report.** The Committee members will each provide an update on the security developments in each of the respective member’s representative segment.

2. **Customs-Trade Partnership Against Terrorism.** The Committee will receive an update on efforts of Customs and Border Protection to revise the security requirements of the program.
Department of Homeland Security

Coast Guard

[Docket No. USCG–2018–0785]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number: 1625–0095

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0095, Oil and Hazardous Material Pollution Prevention and Safety Records, Equivalents/Alternatives and Exemptions; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Comments must reach the Coast Guard and OIRA on or before November 19, 2018.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2018–0785] to the Coast Guard using the Federal eRulemaking Portal at https://www.regulations.gov. Alternatively, you may submit comments to OIRA using one of the following means:

(1) Email: dhshomelandsecurity@omb.eop.gov.  
(2) Mail: OIRA, 725 17th Street NW, Washington, DC 20503, attention Desk Officer for the Coast Guard.


Dated: October 12, 2018.

Jennifer F. Williams, 
Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2018–22813 Filed 10–18–18; 8:45 am]

SUPPLEMENTAL INFORMATION:

Public Participation and Request for Comments

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection’s purpose, the Collection’s likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection. The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, [USCG–2018–0785], and must be received by November 19, 2018.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at https://www.regulations.gov. If your material cannot be submitted using https://www.regulations.gov, contact the person in the FOR FURTHER INFORMATION CONTACT section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at https://www.regulations.gov and can be viewed by following that website’s instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to https://www.regulations.gov and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the Federal Register (70 FR 15086).

OIRA posts its decisions on ICRs online at https://www.reginfo.gov/public/do/PRAMain after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0095.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (83 FR 39768, August 10, 2018) required by 44 U.S.C. 3506(c)(2). That Notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Oil and Hazardous Material Pollution Prevention and Safety Records, Equivalents/Alternatives and Exemptions.

OMB Control Number: 1625–0095.

Summary: The information is used by the Coast Guard to ensure that an oil or hazardous material requirement alternative or exemption provides an equivalent level of safety and protection from pollution.
Need: Under 33 U.S.C. 1321 and Executive Order 12777 the Coast Guard is authorized to prescribe regulations to prevent the discharge of oil and hazardous substances from vessels and facilities and to contain such discharges. Coast Guard regulations in 33 CFR parts 154–156 are intended to: (1) Prevent or mitigate the results of an accidental release of bulk liquid hazardous materials being transferred at waterfront facilities; (2) ensure that facilities and vessels that use vapor control systems are in compliance with the safety standards developed by the Coast Guard; (3) provide equipment and operational requirements for facilities and vessels that transfer oil or hazardous materials in bulk to or from vessels with a 250 or more barrel capacity; and (4) provide procedures for vessel or facility operators who request exemption or partial exemption from Coast Guard regulations in 33 CFR parts 154–156 are intended to: (1) Prevent or mitigate the results of an accidental release of bulk liquid hazardous materials being transferred at waterfront facilities; (2) ensure that facilities and vessels that use vapor control systems are in compliance with the safety standards developed by the Coast Guard; (3) provide equipment and operational requirements for facilities and vessels that transfer oil or hazardous materials in bulk to or from vessels with a 250 or more barrel capacity; and (4) provide procedures for vessel or facility operators who request exemption or partial exemption from compliance with the applicable provisions of the 72 COLREGS.

DATES: The Certificate of Alternative Compliance was issued on October 15, 2018.

FOR FURTHER INFORMATION CONTACT: For information or questions about this certificate call or email Mr. Kevin Miller, First District Towing Vessel/Barge Safety Specialist, U.S. Coast Guard; telephone (617) 223–8272, email Kevin.L.Miller2@uscg.mil.

SUPPLEMENTARY INFORMATION: The United States is a signatory to the International Maritime Organization’s International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), as amended. The special construction or purpose of some vessels makes them unable to comply with the light, shape, or sound signal provisions of the 72 COLREGS. Under statutory law, however, specified 72 COLREGS provisions are not applicable to a vessel of special construction or purpose if the Coast Guard determines that the vessel cannot comply fully with those requirements without interfering with the special function of the vessel.1 The owner, builder, operator, or agent of a special construction or purpose vessel may apply to the Coast Guard District Office in which the vessel is being built or operated for a determination that compliance with alternative requirements is justified,2 and the Chief of the Prevention Division would then issue the applicant a certificate of alternative compliance (COAC) if he or she determines that the vessel cannot comply fully with 72 COLREGS light, shape, and sound signal provisions without interference with the vessel’s special function.3 If the Coast Guard issues a COAC, it must publish notice of this action in the Federal Register.4

The First District Prevention Department, U.S. Coast Guard, certifies that the Blount Boats Inc., Hull TGI–329 is a vessel of special construction or purpose, and that, with respect to the position of the vessels side light, it is not possible to comply fully with the requirements of the provisions enumerated in the 72 COLREGS, without interfering with the normal operation, construction, or design of the vessel. The First District Prevention Department further finds and certifies that the vessel’s sidelights (12’ 1.67” from the vessel’s side mounted on the pilot house) are in the closest possible compliance with the applicable provisions of the 72 COLREGS.5

This notice is issued under authority of 33 U.S.C. 1605(c) and 33 CFR 81.18.


Richard J. Schultz,
Captain, U.S. Coast Guard, Chief, Prevention Division, First Coast Guard District.

[FR Doc. 2018–22855 Filed 10–18–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[1653–0053]

Agency Information Collection Activities: Allegation of Counterfeiting and Intellectual Piracy, Form No. 73–048


ACTION: 30-Day notice and request for comments; extension, without change, of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the Federal Register (83 FR 39771) on August 10, 2018, allowing for a 60-day comment period. USICE received no comments during this period. Based on better estimates, ICE is making an adjustment from the 60-day notice to reflect an increase in the number of respondents. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until November 19, 2018.

ADDRESSES: Interested persons are invited to submit written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden contained in this notice. Comments should be addressed to the Office of Information and Regulatory

1 33 U.S.C. 1605.
2 33 CFR 81.5.
3 33 U.S.C. 1605(c) and 33 CFR 81.18.
SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

1. 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;
2. Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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: Extension, Without Change, of a Currently Approved Collection.
2. Title of the Form/Collection: Allegation of Counterfeiting and Intellectual Piracy.
3. Agency form number, if any, and the applicable component of DHS sponsoring the collection: Form 73–048, USICE.
4. Affected public who will be asked or required to respond, as well as a brief abstract: Primary: Individuals or households. This electronic form/collection will be utilized by the public and law enforcement partners as part of an automated allegation and deconfliction program.
5. An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: 21,711 responses at .5 hours (30 minutes).

6. An estimate of the total public burden (in hours) associated with the collection: 10,855 hours.
7. An estimate of the total public burden (in cost) associated with the collection: $316,860.


Scott Elmore,
PRA Clearance Officer, Office of the Chief Information Officer, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

ENDANGEROUS AND THREATENED SPECIES; RECEIPT OF RECOVERY PERMIT APPLICATIONS

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered or threatened species under the Endangered Species Act, as amended. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before November 19, 2018.

ADDRESSES: Document availability and comment submission: You may, within 30 days of the date of publication of this notice (see DATES), submit requests for copies of the applications and related documents, and submit any comments by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (e.g., TEXXXX):

• Email: permitsR3ES@fws.gov. Please refer to the respective permit number (e.g., Application No. TEXXXX) in the subject line of your email message.

FOR FURTHER INFORMATION CONTACT: Carlita Payne, 612–713–5343; permitsR3ES@fws.gov. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of the Endangered Species Act, as amended (ESA; 16 U.S.C. 1531 et seq.). The requested permits would allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered or threatened under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA’s definition of “take” includes such activities as pursuing, harassing, trapping, capturing, or collecting in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found in the Code of Federal Regulations at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.
### Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. 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 request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

### Next Steps

If we decide to issue permits to any of the applicants listed in this notice, we will publish a notice in the Federal Register.

### Authority

Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).


Lori H. Nordstrom,
Assistant Regional Director, Ecological Services, Midwest Region.

**Editorial Note:** The Office of the Federal Register received this document for publication on October 15, 2018.

**BILLING CODE 4333–15–P**

### DEPARTMENT OF THE INTERIOR

**Fish and Wildlife Service**


**Endangered and Threatened Wildlife; Incidental Take Permit Application, Habitat Conservation Plan for the Sand Skink, Lake County, FL**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; request for comment and information.

**SUMMARY:** We, the Fish and Wildlife Service (Service), have received an application for an incidental take permit (ITP) under the Endangered Species Act. McDonald Ventures XXXVIII, LLC is requesting a 5-year ITP for take of the federally listed sand skink incidental to construction. We request public

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Applicant</th>
<th>Location</th>
<th>Activity</th>
<th>Type of take</th>
<th>Permit action</th>
</tr>
</thead>
<tbody>
<tr>
<td>TE64235B</td>
<td>William O’Leary, Murphyboro, IL</td>
<td>IL, IN, KY</td>
<td>Conduct presence/ab-</td>
<td>Harass, salvage</td>
<td>Renew.</td>
</tr>
<tr>
<td>TE26854C</td>
<td>Brenna Hyzy, Minneapolis, MN</td>
<td>IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, NE, NH, NJ, NY, NC, ND, OH, OK, PA, RI, SC, SD, TN, VT, VA, WV, WI.</td>
<td>Conduct presence/ab-</td>
<td>Add new activity—harp trap</td>
<td>Amend.</td>
</tr>
<tr>
<td>TE71737A</td>
<td>Roger Klocek, Oak Brook, IL</td>
<td></td>
<td>Add new locations—MN to existing authorized locations: IL, IA, OH.</td>
<td>Conduct presence/ab-</td>
<td>Capture, handle, hold, release.</td>
</tr>
</tbody>
</table>
comment on the permit application, which includes the proposed habitat conservation plan, as well as on our preliminary determination that the plan qualifies as low-effect under the National Environmental Policy Act. To make this determination, we used our environmental action statement and low-effect screening form, which are also available for review.

DATES: To ensure consideration, please send your written comments by November 19, 2018.

ADDRESSES: If you wish to review the application, including the HCP, as well as our environmental action statement or low-effect screening form, you may request the documents by email, phone, or U.S. mail. These documents are also available for public inspection by appointment during normal business hours at the office below. Send your comments or requests by any one of the following methods.

Email: northflorida@fws.gov. Use “Attn: TE98747C–0.”
Fax: Field Supervisor, (904) 731–3191. “Attn: TE98747C–0.”
U.S. mail: Field Supervisor, Jacksonville Ecological Services Field Office, Attn: TE99182C–0, U.S. Fish and Wildlife Service, 7915 Baymeadows Way, Suite 200, Jacksonville, FL 32256. In-person drop-off: You may drop off information during regular business hours at the above office address.

FOR FURTHER INFORMATION CONTACT: Erin M. Gawera, telephone: (904) 731–3121; email: erin_gawera@fws.gov.

SUPPLEMENTARY INFORMATION: We, the Fish and Wildlife Service (Service), have received an application for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.). McDonald Ventures XXXVIII, LLC (applicant) is requesting a 5-year ITP to take sand skink (Neoseps reynoldsii) incidental to the conversion of approximately 0.25 acres of occupied sand skink foraging and sheltering habitat for construction of a commercial development. The 9.37-acre project site is located on parcel Number Parcel ID numbers 42226000200000400, 42226000200000500, 42226000200000700, 42226000200000800, and 42226000200000900, within Section 34, Township 22 South, Range 26 East in Lake County, Florida. The project includes the clearing, infrastructure building, and landscaping associated with construction. The applicant proposes to mitigate for the take of the threatened sand skink by purchasing 0.50 mitigation credits within the Lake Wales Ridge Conservation Bank or another Service-approved sand skink conservation bank.

Our Preliminary Determination

We have determined that the Applicant’s proposal, including the proposed mitigation and minimization measures, would have minor or negligible effects on the species covered in the HCP. Therefore, we have determined that the incidental take permit for this project would be “low effect” and qualify for categorical exclusion under the National Environmental Policy Act (NEPA). A low-effect HCP is one involving (1) minor or negligible effects on federally listed or candidate species and their habitats, and (2) minor or negligible effects on other environmental values or resources.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may request in your comment that we withhold your personal identifying information, we cannot guarantee that we will be able to do so.

Next Steps

We will evaluate the HCP and comments we receive to determine whether the ITP application meets the permit issuance requirements of section 10(a) of the ESA. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA. If the requirements for permit issuance are met, we will issue ITP number TE98747C–0 to the Applicant for incidental take of the sand skink.

Authority

We provide this notice under section 10 of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.) and the ESA’s regulations, the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 et seq.) and NEPA regulations (40 CFR 1506.6).

Jay B. Herrington,
Field Supervisor, Jacksonville Field Office, Southeast Region.

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service
[FWS–R8–NWR–2018–N130; FXRS282108E8PD0–190–F2013227943]
South Bay Salt Pond Restoration Project, Phase 2; Don Edwards National Wildlife Refuge, California; Record of Decision for Final Environmental Impact Statement/Environmental Impact Report

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; record of decision.

SUMMARY: We, the U.S. Fish and Wildlife Service, and the California State Coastal Conservancy, announce the availability of the record of decision (ROD) for the Don Edwards National Wildlife Refuge—Phase 2 of the South Bay Salt Pond Restoration Project final environmental impact statement/environmental impact report. The ROD explains that the selected alternative is the environmentally preferred alternative.

ADDRESSES:
Document Availability: The ROD is available at the following places: Internet: http://www.southbayrestoration.org/planning/phase2/.
In Person: San Francisco Bay National Wildlife Refuge Complex Headquarters, 1 Marshlands Rd., Fremont, CA 94555.
FOR FURTHER INFORMATION CONTACT: Chris Barr, Deputy Project Leader, 510–792–0222 (phone), or chris_barr@fws.gov.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), and the California State Coastal Conservancy, announce the availability of the record of decision (ROD) for the final environmental impact statement/environmental impact report (EIS/EIR) for Phase 2 of the South Bay Salt Pond Restoration Project (SBSP) at the Don Edwards National Wildlife Refuge. The ROD explains that the selected alternative is the environmentally preferred alternative.

Background

In December 2007, the USFWS and the California Department of Fish and Wildlife (CDFW) published a Final EIS/EIR for the SBSP Restoration Project at the Don Edwards San Francisco Bay National Wildlife Refuge (Refuge) and the CDFW Eden Landing Ecological Reserve (December 19, 2007; 72 FR 71937). The overall project restoration area includes 15,100 acres, which the USFWS and the CDFW
acquired from Cargill, Inc., in 2003. The lands acquired from Cargill are divided into three pond complexes: the Ravenswood Pond Complex, in San Mateo County, managed by the USFWS; the Alviso Pond complex, also managed by the USFWS, which is mostly in Santa Clara County; and the Eden Landing Pond Complex, in Alameda County, which is owned and managed by the CDFW. The SBSP Restoration Project presented in the Final EIS/EIR was both programmatic, covering a 50-year period, and project-level, addressing the specific components and implementation of Phase 1.

In January 2008, we signed a Record of Decision selecting the Tidal Emphasis Alternative (Alternative C) for implementation. This alternative will result in 90 percent of the USFWS’s ponds on the Refuge being restored to tidal wetlands and 10 percent converted to managed ponds. Under Phase 1 of Alternative C, we restored ponds E8A, E8X, E9, E12, and E13 at the Eden Landing complex; A6, A8, A16, and A17 at the Alviso complex; and SF2 at the Ravenswood complex. We also added several trails, interpretive features, and other recreational access points. Construction was completed on the USFWS ponds in 2013.

Project

The SBSP Phase 2 project site is located on the following three geographically separate pond clusters: the Ravenswood Pond Complex (R3, R4, R5, and S5), the Alviso Pond Complex-Mountain View Ponds (A1 and A2W), the Alviso Pond Complex-A8 Ponds (A8 and A8S), and the Alviso Pond Complex-Island Ponds (A19, A20, and A21). These pond clusters are illustrated in Figures 1–5 on the SBSP Restoration Project website at http://www.southbayrestoration.org/planning/phase2/.

Phase 2 of the SBSP Restoration Project will restore and enhance over 2,000 acres of tidal wetlands and managed pond habitats in South San Francisco Bay while providing for flood management and wildlife-oriented public access and recreation. On June 3, 2016, we announced the availability of the Final EIS/EIR for Phase 2 (81 FR 35790).

Alternatives

We analyzed a range of alternatives in the Final EIS/EIR, including No Action Alternatives for each group of ponds. The range of alternatives included varying approaches to restoring tidal marshes (including number and location of breaches and other levee modifications), habitat enhancements (islands, transition zones, and channels), modifications to existing levees and berms to maintain or improve flood protection, and recreation and public access components (including trails, boardwalks, and viewing platforms) which correspond to the project objectives.

The alternatives for each group of ponds, or pond cluster, are described briefly below. The no-action alternatives are described together, followed by the action alternatives that were considered for each pond cluster.

Alviso-Island Ponds, Alviso-Mountain View Ponds, Alviso-A8 Ponds, and Ravenswood Ponds—Alternatives A (No Action)

Under Alternatives Island A, Mountain View A, A8 A, and Ravenswood A (the no-action alternative at each of these pond clusters), no new activities would be implemented as part of Phase 2. The pond clusters would continue to be monitored and managed through the activities described in the Adaptive Management Plan (AMP) and in accordance with current USFWS practices.

Alviso Island Ponds

Alternative Island B

Alternative Island B would breach Pond A19’s northern levee and remove or lower levees between Ponds A19 and A20 to increase connectivity and improve the ecological function of both ponds.

Alternative Island C

Alternative Island C would include the components of Alternative Island B with the addition of levee breaches on the north sides of Ponds A20 and A21, lowering of portions of levees around Pond A20, pilot channels in Pond A19, and widening the existing breaches on the southern levee of Pond A19.

Alviso-Mountain View Ponds

Alternative Mountain View B

Under Alternative Mountain View B, Ponds A1 and A2W levees would be breached at several points to introduce tidal flow in the ponds. Portions of Pond A1’s western levee would be built up to maintain current levels of flood protection provided by the pond itself. Habitat transition zones and habitat islands would be constructed in the ponds to increase habitat complexity and quality for special-status species. A new trail and viewing platform would be installed to improve recreation and public access at these ponds.

Alternative Mountain View C

Under Alternative Mountain View C, levees would be breached and lowered to increase tidal flows in Pond A1, Pond A2W, and Charleston Slough. The inclusion of Charleston Slough (by breaching and lowering much of Pond A1’s western levees) is the primary distinguishing feature between Alternative Mountain View B and Alternative Mountain View C. Several additional new trails and viewing platforms would be installed or replaced to improve recreation and public access at the pond cluster. To continue providing water to the City of Mountain View’s Shoreline Park sailing lake, a new water intake would be constructed at the proposed breach between Pond A1 and Charleston Slough.

Alviso-A8 Ponds

Alternative A8 B

Alternative A8 B proposes the construction of habitat transition zones in Pond A8S’s southwest corner, southeast corner, or both, depending on the amount of material available.

Ravenswood Ponds

Alternative Ravenswood B

Alternative Ravenswood B would open Pond R4 to tidal flows, improve levees to provide additional flood protection, create habitat transition zone along the western edge of Pond R4, establish managed ponds to improve habitat for diving and dabbling birds, increase pond connectivity, and add a viewing platform to improve recreation and public access.

Alternative Ravenswood C

Alternative Ravenswood C would be similar to Alternative Ravenswood B, with the following exceptions: Ponds R5 and S5 would be converted to a particular type of managed pond that is operated to maintain intertidal mudflat elevation; water control structures would be installed on Pond R3 to allow for improvement to the habitat for western snowy plover; an additional habitat transition zone would be constructed; and two public access and recreational trails and additional viewing platforms would be constructed.

Alternative Ravenswood D

Alternative Ravenswood D would open Pond R4 to tidal flows, improve levees to provide additional flood protection, create two habitat transition zones in Pond R4, establish enhanced managed ponds in Ponds R5 and S5, increase pond connectivity, enhance Pond R3 for western snowy plover
habitat, remove the levees within and between Ponds R5 and S5, and improve recreation and public access.

Alternative Ravenswood D would also allow temporary stormwater detention into Ponds R5 and S5 via connections with the City of Redwood City’s Bayfront Canal and Atherton Channel Project. This would treat a residual salinity problem in Ponds R5 and S5.

Following public review of the Draft EIS/EIR, USFWS and the California State Coastal Conservancy, in coordination with the Project Management Team and other project partners, identified the preferred alternative, which is based on restoration enhancements at all four pond clusters, as well as maintained or increased flood protection and additional public access and recreation features at two of the Phase 2 pond clusters. The preferred alternative is described in Chapter 6 of the Final EIS/EIR. A summary is provided below.

**Preferred Alternative:** The preferred alternative at each pond cluster is as follows:

- **At the Island Ponds** it is Alternative Island B, with one restoration component of Alternative Island C included, which is to widen only the westernmost of the two existing breaches on the south side of Pond A19.
- **At the Mountain View Ponds** it is essentially Alternative Mountain View B, with the substitution of one habitat enhancement (do not include Charleston Slough in tidal marsh restoration but do construct a habitat transition zone across the entire southern extent of Pond A1, but only across central portion of A2W) and the addition of one public access component drawn from Mountain View C (add recreational trail on eastern levee of Pond A2W to the northeast corner of Pond A2W). There is also a modification of one of the flood protection features presented in the two action alternatives (raise the Coast Casey Forebay levee along southern border of Charleston Slough and maintain necessary access to existing utilities adjacent to that levee).
- **At the A8 Ponds** it is Alternative A8 B, except that the top elevation of the proposed transition zones has been increased to provide greater erosion protection.
- **At the Ravenswood Ponds** it is similar to Alternative Ravenswood B, in its restoration goals and features for Ponds R3, R4, R5, and S5, but it also includes an additional habitat transition zone and a trail on the eastern edge of Ponds R5 and S5, all of which were included in Alternatives Ravenswood C and D.

## Selected Alternative

The ROD identifies the preferred alternative as the selected alternative. This alternative is also the environmentally preferred alternative. The basis for the decision, descriptions of the alternatives considered, an overview of the measures to be implemented to avoid and minimized environmental effects, and a summary of the public involvement process are provided in the ROD.

### Authority

We publish this notice under the authority of the National Environmental Policy Act (42 U.S.C. 4371 et seq.) and the Department of Interior’s implementing regulations in title 43 of the Code of Federal Regulations (43 CFR part 46).

**Jody Holzworth,**

*Acting Regional Director, Pacific Southwest Region.*

[FR Doc. 2018–22763 Filed 10–18–18; 8:45 am]

**BILLING CODE 4333–15–P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

**Final Environmental Impact Statement on American Electric Power’s American Burying Beetle Habitat Conservation Plan in Arkansas, Oklahoma, and Texas**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, under the National Environmental Policy Act, make available the final environmental impact statement analyzing the impacts of issuance of an incidental take permit (ITP) for implementation of American Electric Power’s American Burying Beetle Habitat Conservation Plan in Arkansas, Oklahoma, and Texas (HCP). Our decision is to issue a 30-year ITP for implementation of the HCP, which authorizes incidental take of the American burying beetle under the Endangered Species Act.

**DATES:** We will finalize a record of decision and issue a permit no sooner than November 19, 2018.

**ADDRESSES:** You may obtain copies of the documents in the following formats:

- **Electronic:**
  - [https://www.fws.gov/southwest/es/Oklahoma/](https://www.fws.gov/southwest/es/Oklahoma/)
  - CD-ROM: Contact Ms. Jonna Polk (see FOR FURTHER INFORMATION CONTACT).

- **Hard copy:** You may review the final environmental impact statement (EIS) at the following locations (by appointment only):

**FOR FURTHER INFORMATION CONTACT:** Jonna Polk, Field Supervisor, via U.S. mail at Oklahoma Ecological Services Field Office, U.S. Fish and Wildlife Service, 9014 E. 21st St., Tulsa, OK 74129; or via phone at 918–581–7458.

**SUPPLEMENTARY INFORMATION:** We, the U.S. Fish and Wildlife Service (Service), announce the availability of several documents related to an incidental take permit (ITP) application under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.). The final EIS was developed in compliance with the agency decision-making requirements of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 et seq.), and is based on the habitat conservation plan (HCP) as submitted by American Electric Power (applicant). We described, fully evaluated, and analyzed all three alternatives in detail in our 2018 final EIS.

Our proposed action is to issue an ITP to the applicant under section 10(a)(1)(B) of the ESA that authorizes incidental take of the American burying beetle (*Nicrophorus americanus*; ABB) from the applicant’s maintenance, operation, and expansion of its electrical facilities in Oklahoma, Arkansas, and Texas. American Electric Power is one of the largest electric utilities in the country, with an electric system that includes transmission lines, substations, switching stations, and a distribution network. American Electric Power’s ability to serve its customers depends on the timely installation, operation, and maintenance of its electric facilities. The plan area for the HCP includes areas where authorized incidental take would occur and conservation measures would take place, a total of almost 32 million acres. The applicant requested a term of 30 years from the date of ITP issuance. The
applicant will fully implement minimization and mitigation measures to offset impacts to the ABB according to the HCP.

The applicant has agreed to include the following minimization measures:
- Reducing erosion by implementing stormwater best practices;
- Limiting use of motor vehicles, machinery, or heavy equipment in occupied ABB habitat to avoid soil compaction;
- Increasing safety during operation and permanent storage;
- Limiting disturbance from mechanical vegetation management;
- Limiting the use of artificial lighting in occupied ABB habitat; and
- Providing a training program for all personnel conducting or supervising covered activities that may disturb ABB-occupied habitat.

The mitigation measures include the following commitments:
- Relieve soil compaction by disking (mechanically breaking up) compacted soil in laydown areas and material storage areas;
- Revegetate with a native species composition similar to that of the surrounding area (typically warm season grasses) or of the same vegetation type that existed prior to impacts for areas that experienced ground disturbance causing temporary or permanent cover change habitat impacts; and
- Establish off-site habitat mitigation for temporary or permanent cover change and permanent impacts.

In addition to this notice, the Environmental Protection Agency (EPA) is publishing a notice announcing the EIS, as required under the Clean Air Act, section 309 (42 U.S.C. 7401 et seq.) and NEPA (42 U.S.C. 4321 et seq.), see EPA’s Role in the EIS Process below.

Background

The applicant has applied for an ITP under the ESA that would authorize incidental take of the ABB and would be in effect for a period of 30 years. The proposed incidental take of the ABB would occur from lawful, non-Federal activities from the applicant’s repair, maintenance, and construction activities for electrical lines and support facilities (e.g., substations and switching facilities) within the plan area, as well as from activities carried out as part of the HCP’s conservation strategy (covered activities). The HCP plan area includes Oklahoma and Arkansas counties within known ABB ranges and Texas counties with ABB occurrence records. The plan area also includes counties in these States where the ABB’s range could expand over the ITP.
of the eleven landowners, collectively known as the Eastern Collier Property Owners, LLC, requests a 50-year ITP authorizing take of the Florida panther and 18 other Federal or State-listed species incidental to residential and commercial development, earth mining, and low-intensity rural-land activities in a defined portion of Collier County, Florida.

**DATES:** Comments: We will accept comments received or postmarked on or before December 3, 2018. Comments submitted electronically at [http://www.regulations.gov](http://www.regulations.gov) must be received by 11:59 p.m. Eastern time on the closing date. Any comments we receive after the closing date may not be considered in the final decision on these actions.

**ADDRESSES:**

**Obtain Documents:** You may obtain copies of the EIS and HCP by the following methods:
- Field Office: [https://www.fws.gov/verobeach/](https://www.fws.gov/verobeach/).

**Submit Comments:** You may submit written comments by one of the following methods:


**FOR FURTHER INFORMATION CONTACT:** Mr. David Dell, Regional HCP Coordinator, by mail at Attn: ECPO; U.S. Fish and Wildlife Service; 1875 Century Boulevard, Atlanta, GA 30345 or by telephone at 404–679–7313, or Dr. Constance Cassler, Supervisory Fish and Wildlife Biologist, by mail to the South Florida Ecological Services Office, Attn: ECPO; U.S. Fish and Wildlife Service, 1339 20th Street, Vero Beach, FL 32960 or by telephone at 772–469–4356.

**SUPPLEMENTARY INFORMATION:** We, the U.S. Fish and Wildlife Service (Service), have received applications for ITPs under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.).

**Applicants:** The Eastern Collier Property Owners, LLC (ECPO/Applicants) was formed as a collaborative effort to address long-term land-use planning and conservation issues related to the Florida panther in the east Collier County area (see also [http://www.floridapantherprotection.com](http://www.floridapantherprotection.com)). The Applicants’ collaboration culminated in the HCP, which supports their collective application for the issuance of 50-year ITPs for take of the Florida panther and 18 other covered species. Table 1, below, individually lists the ECPO members and their Service-assigned application numbers. Table 2 depicts the species covered by the HCP.

<table>
<thead>
<tr>
<th>TABLE 1—MEMBERS OF EASTERN COLLIER PROPERTY OWNERS, LLC, AND THEIR INCIDENTAL TAKE PERMIT APPLICATION NUMBERS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Applicants</strong></td>
</tr>
<tr>
<td>Alico Land Development, Inc</td>
</tr>
<tr>
<td>Barron Collier Investment, Ltd</td>
</tr>
<tr>
<td>Collier Enterprises Management, Inc</td>
</tr>
<tr>
<td>Consolidated Citrus Limited Partnership</td>
</tr>
<tr>
<td>English Brothers Partnership</td>
</tr>
<tr>
<td>Half Circle L Ranch, LLP</td>
</tr>
<tr>
<td>Heller Bros. Packing Corp</td>
</tr>
<tr>
<td>JB Ranch I, LLC</td>
</tr>
<tr>
<td>Owl Hammock Immokalee, LLC</td>
</tr>
<tr>
<td>Pacific Land, Ltd</td>
</tr>
<tr>
<td>Sunland Family Limited Partnership</td>
</tr>
</tbody>
</table>

**Background**

Section 9 of the ESA and its implementing regulations prohibit “take” of Federally-listed “threatened” or “endangered” fish and wildlife species. However, section 10(a) of the Act provides exceptions to the prohibition by allowing us to issue permits authorizing take of listed species where such take is incidental to, and not the purpose of, otherwise lawful activities and where the applicant meets certain statutory requirements.

The Applicants’ HCP proposes a programmatic approach and framework for engaging in incidental take of the covered species while providing for the permanent protection of portions of the covered lands via conservation easements and generating funding for conservation activities for the covered species in addition to those provided in the HCP. The individual Applicants collectively own a total of 151,779 acres within the approximately 174,000-acre HCP planning area. Under the HCP, up to 45,000 acres could be developed or
used for other activities. Impacts to covered species from the activities would be mitigated through habitat management measures and the placement of conservation easements on up to 107,000 acres of the covered lands. The Applicants also propose to make contributions to a conservation endowment, the Marinelli Fund, to implement conservation measures for the covered species throughout and beyond the covered lands.

Draft Environmental Impact Statement

We published a notice of intent to prepare an EIS for this HCP in the Federal Register on March 25, 2016 (81 FR 16200). A public scoping meeting was held in Naples, Florida on April 12, 2016, and an online public participation webcast was conducted on April 19, 2016. We have incorporated issues identified during these scoping meetings into the draft EIS. A summary of the comments received during the scoping period is provided in the Scoping Report appended to the draft EIS.

The draft EIS assesses the likely environmental impacts associated with the implementation of the activities proposed in the HCP, compared to the likely consequences of not issuing the requested ITPs, i.e., uncoordinated project-by-project and lot-by-lot planning and mitigation as currently occurs. The Department of the Army, through its bureau the U.S. Army Corps of Engineers, Jacksonville District, is a cooperating agency in the development of the draft EIS.

Public Comments

If you wish to comment on the HCP, or draft EIS, you may submit comments by any one of the methods listed above in ADDRESSES. Before including your address, phone number, email address, or other personal identifying information in your comment, be aware that we will include any personal information you provide us in the text of our response to your comment—ranging from your name to your email address to your phone number. We cannot guarantee that we will be able to do so.

Next Steps

We will evaluate the HCP, draft EIS, and your comments to determine whether the collective ITP application meets the permit issuance requirements of section 10(a) of the ESA. We will also conduct an intra-Service consultation pursuant to section 7 of the ESA. If the requirements for permit issuance are met, we will issue individual ITPs to the Applicants.

Authority

We provide this notice under section 10 of the ESA (16 U.S.C. 1531 et seq.) and ESA regulations in title 50 of the Code of Federal Regulations and, the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 et seq.) and NEPA regulations (40 CFR 1506.6).

Mike Oetker, Acting Regional Director, Southeast Region.

[FR Doc. 2018–22755 Filed 10–18–18; 8:45 am] BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2018–N022; FXES11130800000–189–FF08EVEN00]

Endangered and Threatened Wildlife and Plants; Availability of Habitat Conservation Plan and Categorical Exclusion for the Mount Hermon June Beetle, Santa Cruz County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application from Lantana, LLC for a 5-year incidental take permit under the Endangered Species Act of 1973, as amended (Act). The permit would authorize "take" of the federally endangered Mount Hermon June beetle, incidental to the otherwise lawful activities associated with the demolition of a single-family home and construction of two duet homes at 22 Blake Lane, Scotts Valley, Santa Cruz County, California. We invite comments from the public on the application package, which includes a low-effect habitat conservation plan.

DATES: To ensure consideration, please send your written comments by November 19, 2018.

ADDRESSES: You may download a copy of the draft habitat conservation plan, draft environmental action statement, and draft low-effect screening form at http://www.fws.gov/ventura/, or you may request copies of the documents by U.S. mail to our Ventura office or by phone (see FOR FURTHER INFORMATION CONTACT). Please address written comments to Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003. You may alternatively send comments by facsimile to (805) 644–3958.

FOR FURTHER INFORMATION CONTACT: Karen Sinclair, Fish and Wildlife Biologist, by U.S. mail to the Ventura address in ADDRESSES, or by telephone at (805) 677–3315.

SUPPLEMENTARY INFORMATION: We have received an application from Lantana, LLC for a 5-year incidental take permit under the Act. The application addresses the potential for take of the federally endangered Mount Hermon June beetle (Polyphylla barbata) likely to occur incidental to the demolition of a single-family home and construction of two duet homes at 22 Blake Lane, Scotts Valley, Santa Cruz County, California. We invite comments from the public on the application package, which includes the Low-Effect Habitat Conservation Plan (HCP) for the Mount Hermon June Beetle.

Background

The U.S. Fish and Wildlife Service (Service) listed the Mount Hermon June beetle as endangered on January 24, 1997 (62 FR 3616). Section 9 of the Act (16 U.S.C. 1531 et seq.) and its implementing regulations prohibit the take of fish or wildlife species listed as endangered or threatened. "Take" is defined under the Act to include the following activities: "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct" (16 U.S.C. 1532); however, under section 10(a)(1)(B) of the Act, we may issue permits to authorize incidental take of listed species. The Act defines "Incidental Take" as take that is incidental to, and not the purpose of carrying out an otherwise lawful activity. Regulations governing incidental take permits for threatened and endangered species are in the Code of Federal Regulations (CFR) at 50 CFR 17.32 and 17.22, respectively. Issuance of an incidental take permit must not jeopardize the existence of federally listed fish, wildlife, or plant species. All species covered by the incidental take permit associated with this low-effect HCP receive assurances under our "No Surprises" regulations (50 CFR 17.22(b)(5) and 17.32(b)(5)).

Applicant’s Proposal

Lantana, LLC (hereafter, the applicant) has submitted a low-effect HCP in support of their application for an incidental take permit (ITP) to address take of the Mount Hermon June beetle that is likely to occur as the result of direct impacts on up to 0.32 acre (ac) (14,031 square feet (sf)) of degraded
sandhills habitat occupied by the species. Take would be associated with the demolition of a single-family home and construction of two duet homes on a parcel legally described as Assessor Parcel Number: 022–172–47. The current site address is 22 Blake Lane in Scotts Valley, Santa Cruz County, California. The applicant is requesting a permit for take of Mount Hermon June beetle that would result from “covered activities” that are related to the demolition of a single-family home and construction of two duet homes at 22 Blake Lane.

The applicant proposes to avoid, minimize, and mitigate take of Mount Hermon June beetle associated with the covered activities by fully implementing the HCP. The following measures will be implemented: (1) Locating the project on a developed parcel where habitat is more degraded relative to intact habitat; (2) Avoiding the flight season, if possible, and using plastic sheeting or other soil-covering material to prevent Mount Hermon June beetles from burrowing into exposed soil in the construction site when/if soil disturbing activities must occur between May and August; (3) Having a qualified biologist translocate any larval beetles unearthed during construction activities to a portion of the project site outside of the impact area that supports intact vegetation; (4) Minimizing hardscaping associated with the project, and using native Sandhills plants and non-invasive ornamental plants in landscape areas; (5) Minimizing removal of native trees on the site, including the ponderosa pines and coast live oaks; (6) Revegetating areas of temporary habitat disturbance with native and non-invasive ornamental plants that do not degrade Mount Hermon June beetle habitat; and (7) Securing off-site mitigation at a ratio of 1:1 to mitigate for habitat impacts through the acquisition of 0.32 ac (14,031 sf) of conservation credits at the Zayante Sandhills Conservation Bank. The applicant will fund all elements of the proposed conservation strategy to ensure implementation of all minimization measures, monitoring, and reporting requirements identified in the HCP.

Our Preliminary Determination

The Service has made a preliminary determination that issuance of the incidental take permit is neither a major Federal action that will significantly affect the quality of the human environment within the meaning of section 102(2)(C) of NEPA (42 U.S.C. 4321 et seq.) nor that it will, individually or cumulatively, have more than a negligible effect on the Mount Hermon June beetle, the only species covered in the HCP. Therefore, the permit qualifies for a categorical exclusion under NEPA.

Public Review

We request comments on our determination that the applicant’s proposal will have a minor or negligible effect on the Mount Hermon June beetle and that the plan qualifies as a low-effect HCP. We will evaluate the permit application, including the plan and comments we receive, to determine whether the application meets the requirements of section 10(a)(1)(B) of the Act. We will use the results of our internal Service consultation, in combination with the above findings, in our final analysis to determine whether to issue the ITP. If the requirements are met, we will issue the ITP to the applicant. We will make the final permit decision no sooner than 30 days after the publication date of this notice.

Public Comments

If you wish to comment on the permit application, HCP, and associated documents, you may submit comments by any one of the methods in ADDRESSES.

Public Availability of Comments

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 in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 et seq.) and NEPA regulations (40 CFR 1506.6).

Dated: October 11, 2018.

Stephen P. Henry,
Field Supervisor, Ventura Fish and Wildlife Office.

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Data Elements for Student Enrollment in Bureau-Funded Schools

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Bureau of Indian Education (BIE) are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before November 19, 2018.

ADDRESSES: Send written comments on this information collection request (ICR) to the Office of Management and Budget’s Desk Officer for the Department of the Interior by email at OIRA_Submission@omb.eop.gov; or via facsimile to (202) 395–5806. Please provide a copy of your comments to Dr. Joe Herrin, Bureau of Indian Education, 1840 C Street NW, MS–3620–MB, Washington, DC 20240; facsimile: (202) 208–7658; email: Joe.Herrin@BIE.edu. Please reference OMB Control Number 1076–0122 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Dr. Joe Herrin, phone: (202) 208–7658. You may also view the ICR at http://www.reginfo.gov/public/do/PRAMain.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public’s reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format. A Federal Register notice with a 60-day public comment period soliciting comments on this collection of information was published on April 9, 2018 (83 FR 15174). No comments were received.
We are again soliciting comments on the proposed ICR that is described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of the BIE; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the BIE enhance the quality, utility, and clarity of the information to be collected; and (5) how might the BIE minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. 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 in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The BIE is requesting renewal of OMB approval for the form submitted for the Bureau Enrollment Application in Bureau-funded Schools. School registrars collect information on this form to determine the student’s eligibility for enrollment in a Bureau-funded school, and if eligible, is shared with appropriate school officials to identify the student’s base and supplemental educational and/or residential program needs. The BIE compiles the information into a national database to facilitate budget requests and the allocation of congressionally appropriated funds.

Title of Collection: Data Elements for Student Enrollment in Bureau-funded Schools.

OMB Control Number: 1076–0122.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Bureau funded Contract and Grant schools.

Total Estimated Number of Annual Respondents: 48,000 per year, on average.

Total Estimated Number of Annual Responses: 48,000 per year, on average.

Estimated Completion Time per Response: 15 minutes.

Total Estimated Number of Annual Burden Hours: 12,000 hours.

Respondent’s Obligation: Required to Obtain a Benefit.

Frequency of Collection: Once per year.

Total Estimated Annual Nonhour Burden Cost: $0.

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 authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Elizabeth K. Appel, Director, Office of Regulatory Affairs and Collaborative Action—Indian Affairs.

[FR Doc. 2018–22816 Filed 10–18–18; 8:45 am]

BILLING CODE 4377–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0026439; PPWOCRADN0–PCU00RP14,RS0000]

Notice of Inventory Completion: Fowler Museum at the University of California Los Angeles, Los Angeles, CA; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

SUMMARY: The Fowler Museum at the University of California Los Angeles (UCLA) has completed an inventory of human remains and associated funerary objects, published in a Notice of Inventory Completion in the Federal Register on January 27, 2016. This notice directs the minimum number of individuals and associated funerary objects. Lineal descendants or representatives of any Native American organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Fowler Museum at UCLA. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Native American organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Fowler Museum at UCLA. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

ADDITIONAL INFORMATION:

This notice provides a minimum number of individuals and associated funerary objects published in a Notice of Inventory Completion of the Federal Register (81 FR 4662–4670, January 27, 2016). A re-inventory discovered more human remains and associated funerary objects than was previously recorded. Transfer of control of the items in this correction notice has not occurred.

Correction

In the Federal Register (81 FR 4663, January 27, 2016), column 2, paragraph 4, sentence 1 is corrected by substituting the following sentence:

At an unknown date between 1900 and 1950, human remains representing, at minimum, 26 individuals were removed from Sequit Creek Indian Mound (CA–LAN–52) in Los Angeles County, CA.

In the Federal Register (81 FR 4663, January 27, 2016), column 2, paragraph 4, sentence 5 is corrected by substituting the following sentence:

The fragmentary human remains represent 20 adults, sex unknown, one subadult individual (sex unknown), three juvenile individuals (sex unknown) and two infants (sex unknown).

In the Federal Register (81 FR 4667, January 27, 2016), column 2, paragraph 4, sentence 7 is corrected by substituting the following sentence:

The two associated funerary objects include two unmodified faunal bones.

In the Federal Register (81 FR 4667, January 27, 2016), column 3, paragraph 2, sentence 1 is corrected by substituting the following sentence:

At an unknown date, human remains representing, at minimum, four individuals...
were removed from San Miguel Island (CA–SMI–xxx) in Santa Barbara County, CA, from private ranching land. Likely in the 1920s, by Dr. Guy C. Rich and given to Loye Miller of the UCLA Biology Department and accessioned within the Dickey Bird and Mammal Collection.

In the Federal Register (81 FR 4667, January 27, 2016), column 3, paragraph 2, sentence 5 is corrected by substituting the following sentence:

The fragmentary human remains represent four individuals of unknown age and sex.

In the Federal Register (81 FR 4670, January 27, 2016), column 2, paragraph 2, sentence 1 is corrected by substituting the following sentence:

• Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 1,827 individuals of Native American ancestry.

In the Federal Register (81 FR 4670, January 27, 2016), column 2, paragraph 2, sentence 2 is corrected by substituting the following sentence:

• Pursuant to 25 U.S.C. 3001(3)[A], the 46,017 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Wendy G. Teeter, Ph.D., Fowler Museum at UCLA, Box 951549, Los Angeles, CA 90095–1549, telephone (310) 825–1864, email wteeter@arts.ucla.edu, by November 19, 2018. See the Federal Register (81 FR 4670, January 27, 2016), column 3, paragraph 2, sentence 5 is corrected by substituting the following sentence:

• Pursuant to 25 U.S.C. 3001(3)[B], the 132 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from the specific burial sites of Native American individuals.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California.

The Fowler Museum is responsible for notifying the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California that this notice has been published.

Dated: September 6, 2018.
Melanie O’Brien, Manager, National NAGPRA Program.

DEPARTMENT OF THE INTERIOR
National Park Service

[NS–WASO–NAGPRA–NPS90002441; PPWOCRADN0–PCU00RP14,R50000]

Notice of Intent To Repatriate Cultural Items: Fowler Museum at the University of California Los Angeles, Los Angeles, CA

AGENCY: National Park Service, Interior. ACTION: Notice.

SUMMARY: The Fowler Museum at the University of California Los Angeles (UCLA), in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the Fowler Museum at UCLA. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Fowler Museum at UCLA at the address in this notice by November 19, 2018.

ADDRESSES: Wendy G. Teeter, Ph.D., Fowler Museum at UCLA, Box 951549, Los Angeles, CA 90095–1549, telephone (310) 825–1864, email wteeter@arts.ucla.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Fowler Museum at UCLA that meet the definition of unassociated funerary objects under 25 U.S.C. 3001. This notice is published as part of the National Park Service’s administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

In 1978 and 1979, 132 cultural items were removed from Lindero Canyon (CA–VEN–606) in Ventura County, CA. Collections from the site derive from the survey and excavation undertaken during the North Ranch Inland Chumash research project, led by Dr. William Clewlow Jr., on land privately owned by the Prudential Insurance Company. A cemetery was discovered during the 1979 excavations. Thirteen burials were uncovered and left in-situ, but burial objects were removed for study. The unassociated funerary objects were removed from six of the burials and were transferred to UCLA in 1979. The site has been dated to the Late Period, A.D. 1300–1650. The 132 unassociated funerary objects are: 12 pieces and four bags of shell fragments, two shell beads, 62 stone flakes, one cobble, three quartz crystals, 41 pieces and two bags of unmodified animal bone fragments, four ochre fragments, and one charcoal lump.

Determinations Made by the Fowler Museum at UCLA

Officials of the Fowler Museum at UCLA have determined that:

• Pursuant to 25 U.S.C. 3001(3)[B], the 132 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from the specific burial sites of Native American individuals.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Dr. Wendy G. Teeter, Fowler Museum at UCLA, Box 951549, Los Angeles, CA 90095–1549, telephone (310) 825–1864, email wteeter@arts.ucla.edu.

After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California may proceed.
DEPARTMENT OF THE INTERIOR
National Park Service

Notice of Inventory Completion: Department of Anthropology at Indiana University, Bloomington, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology at Indiana University has completed an inventory of human remains in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Indiana University NAGPRA Office. If no additional requestors come forward, transfer of control of the human remains to The Tribes may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Jayne-Leigh Thomas, NAGPRA Director, Indiana University, NAGPRA Office, Student Building 318, 701 E Kirkwood Avenue, Bloomington, IN 47405, telephone (812) 856–5315, email thomajay@indiana.edu, by November 19, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

DEPARTMENT OF THE INTERIOR
National Park Service

Notice of Inventory Completion: Department of Anthropology at Indiana University, Bloomington, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology at Indiana University has completed an inventory of human remains in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal}

The Fowler Museum at UCLA is responsible for notifying the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California that this notice has been published.

Dated: September 6, 2018.

Melanie O’Brien, Manager, National NAGPRA Program.

DEPARTMENT OF THE INTERIOR
National Park Service

Notice of Inventory Completion: Department of Anthropology at Indiana University, Bloomington, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology at Indiana University has completed an inventory of human remains and associated funerary objects under the control of the Department of Anthropology at Indiana University, Bloomington, IN. The human remains were removed from an unknown location.

This notice is published as part of the National Park Service’s administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by Indiana University professional staff in consultation with representatives of the Alabama-Coushatta Tribe of Texas (previously listed as the Alabama-Coushatta Tribes of Texas); Alabama-Quassarte Tribal Town; Coushatta Tribe of Louisiana; Kialege Tribal Town; Miccosukee Tribe of Indians of Florida; Poarch Band of Creeks (previously listed as the Poarch Band of Creek Indians of Alabama); Seminole Tribe of Florida (previously listed as the Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations)); The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; and the Thlopthlocco Tribal Town, hereafter referred to as “The Tribes.”

History and Description of the Remains

In 1956, human remains representing, at minimum, one individual were donated to the Department of Anthropology at Indiana University from the Cincinnati Society of Natural History. Notes indicate that these human remains may have been part of the Chicago Historical Society collections prior to 1950. The human remains are labeled as being from a Creek individual. No other information is present. No known individuals were identified. No associated funerary objects are present.

Descendants of the Creek Confederacy are members of the federally-recognized tribes of the Alabama-Quassarte Tribal Town, Oklahoma; Kialege Tribal Town, Oklahoma; Muscogee (Creek) Nation, Oklahoma; Poarch Band of Creek Indians of Alabama; Alabama-Coushatta Tribe of Texas; Coushatta Tribe of Louisiana; Seminole Nation of Oklahoma; Seminole Tribe of Florida; Miccosukee Tribe of Indians of Florida; and the Thlopthlocco Tribal Town, Oklahoma.

Determinations Made by the Department of Anthropology at Indiana University

Officials of the Department of Anthropology at Indiana University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Jayne-Leigh Thomas, NAGPRA Director, Indiana University, NAGPRA Office, Student Building 318, 701 E Kirkwood Avenue, Bloomington, IN 47405, telephone (812) 856–5315, email thomajay@indiana.edu, by November 19, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Indiana University NAGPRA Office is responsible for notifying The Tribes that this notice has been published.

Dated: September 6, 2018.

Melanie O’Brien, Manager, National NAGPRA Program.
descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Indiana University NAGPRA Office. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

**DATES:** Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Indiana University NAGPRA Office at the address in this notice by November 19, 2018.

**ADDRESSES:** Dr. Jayne-Leigh Thomas, NAGPRA Director, Indiana University, NAGPRA Office, Student Building 318, 701 E Kirkwood Avenue, Bloomington, IN 47405, telephone (812) 856–5315, email thomajay@indiana.edu.

**SUPPLEMENTARY INFORMATION:** Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Department of Anthropology at Indiana University, Bloomington, IN. The human remains were removed from an unknown location.

This notice is published as part of the National Park Service’s administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

**Consultation**

A detailed assessment of the human remains was made by Indiana University professional staff in consultation with representatives of Alabama-Coushatta Tribe of Texas (previously listed as the Alabama-Coushatta Tribes of Texas); Alabama-Quassarte Tribal Town; Coushatta Tribe of Louisiana; Jena Band of Choctaw Indians; Mississippi Band of Choctaw Indians; Poarch Band of Creek Indians; Seminole Tribe of Florida (previously referred to as the Seminole Tribe of Florida (Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations)); The Chocotaw Nation of Oklahoma; The Muscogee (Creek) Nation; The Seminole Nation of Oklahoma; and the Thlopthlocco Tribal Town, hereafter referred to as “The Tribes.”

**History and Description of the Remains**

In 1956, human remains representing, at minimum, one individual were donated to the Department of Anthropology at Indiana University from the Cincinnati Society of Natural History. Notes indicate that these human remains may have been part of the Chicago Historical Society collections prior to 1950. The human remains are labeled as being from a Choctaw-Creek individual. No other information is present. Choctaw descendants are members of the federally-recognized tribes of The Chocotaw Nation of Oklahoma, the Jena Band of Choctaw Indians, and the Mississippi Band of Choctaw Indians. Descendants of the Creek Confederacy are members of the federally-recognized tribes of the Alabama-Quassarte Tribal Town, Oklahoma; Kialeege Tribal Town, Oklahoma; Muscogee (Creek) Nation, Oklahoma; Poarch Band of Creek Indians of Alabama; Alabama-Coushatta Tribe of Texas; Coushatta Tribe of Louisiana; Seminole Nation of Oklahoma; Seminole Tribe of Florida; Miccosukee Tribe of Indians of Florida; and the Thlopthlocco Tribal Town, Oklahoma.

**Determinations Made by the Department of Anthropology at Indiana University**

Officials of the Department of Anthropology at Indiana University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Tribes.

**Additional Requestors and Disposition**

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Jayne-Leigh Thomas, NAGPRA Director, Indiana University, NAGPRA Office, Student Building 318, 701 E Kirkwood Avenue, Bloomington, IN 47405, telephone (812) 856–5315, email thomajay@indiana.edu, by November 19, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Indiana University NAGPRA Office is responsible for notifying The Tribes that this notice has been published.

**DEPARTMENT OF THE INTERIOR**

**National Park Service**

[PPWOCRDN0–PCU00RP14.R50000]

**Notice of Inventory Completion: Fowler Museum at the University of California Los Angeles, Los Angeles, CA**

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice.

**SUMMARY:** The Fowler Museum at the University of California Los Angeles (UCLA) has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Fowler Museum at UCLA. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

**DATES:** Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Fowler Museum at UCLA at the address in this notice by November 19, 2018.

**ADDRESSES:** Wendy G. Teeter, Ph.D., Fowler Museum at UCLA, Box 951549, Los Angeles, CA 90095–1549, telephone (310) 825–1864, email wteeter@arts.ucla.edu.

**SUPPLEMENTARY INFORMATION:** Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C.
3003, of the completion of an inventory of human remains under the control of the Fowler Museum at UCLA, Los Angeles, CA. The human remains were removed from San Diego County, California.

This notice is published as part of the National Park Service’s administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation
A detailed assessment of the human remains was made by the Fowler Museum at UCLA professional staff in consultation with representatives of the Campo Band of Diegueño Mission Indians of the Campo Indian Reservation, California; Capitan Grande Band of Diegueño Mission Indians of California (Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California; Ewiaapaayp Band of Kumeyaay Indians, California; lipay Nation of Santa Ysabel, California (previously listed as the Santa Ysabel Band of Diegueño Mission Indians of the Santa Ysabel Reservation); Inaja Band of Diegueño Mission Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; La Posta Band of Diegueño Mission Indians of the La Posta Indian Reservation, California; Manzanita Band of Diegueño Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueño Mission Indians of the Mesa Grande Reservation, California; San Pasqual Band of Diegueño Mission Indians of California; and Sycuan Band of the Kumeyaay Nation (hereafter referred to as “The Tribes”).

History and Description of the Remains
In 1958 and 1959, human remains representing, at minimum, three individuals were collected from CA–SDI–525 (W–9) in San Diego County, CA, by Carl L. Hubbs, G. Shumway, J.R. Moriarty, and Claude Warren in the course of conducting excavations at the site during the construction of two homes in Scripps Estates. The site dates to the Middle Holocene (between 7,000 and 5,500 B.P.) based on radiocarbon dating. Altogether, 16 burials were uncovered, seven of which were left in situ. In 1959, the collections of the other nine burials were sent to UCLA. Subsequently, the collections from seven of these burials were transferred to the University of California, Scripps Institution of Oceanography, while the collections from Burials 9 and 10 remained at UCLA. The identified human remains from Burials 9 and 10 were reportedly sent to “Stanford” for dating. Despite extensive investigations, at this time, the Fowler Museum at UCLA cannot locate these human remains. The human remains in this notice are fragments that were found with faunal remains. They represent two juvenile individuals of unknown sex and one individual of undetermined age and sex. No known individuals were identified. No associated funerary objects were identified.

Based on archeological evidence, geographic location, ethnographic information, and oral history evidence, these human remains have been identified as Native American. Site CA–SDI–525 has been identified through consultation with The Tribes to be within the lands traditionally occupied by the Kumeyaay Nation, which is composed of The Tribes.

Determinations Made by the Fowler Museum at UCLA
Officials of the Fowler Museum at UCLA have determined that:

• Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Tribes.

Additional Requestors and Disposition
Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Fowler Museum at UCLA. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Fowler Museum at UCLA at the address in this notice by November 19, 2018.

ADDRESSES: Wendy G. Teeter, Ph.D., Fowler Museum at UCLA, Box 951549, Los Angeles, CA 90095–1549, telephone (310) 825–1864, email wteeter@arts.ucla.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the correction of an inventory of human remains under the control of the Fowler Museum at UCLA, Los Angeles, CA. The human remains were removed from Los Angeles County, CA.

This notice is published as part of the National Park Service’s administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.
The Field Museum has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Field Museum. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request and the appropriate Federal agency that has control of the Native American human remains and associated funerary objects should submit a written request with information in support of the request to the Field Museum at the address in this notice by November 19, 2018.

ADDRESSES: Helen Robbins, The Field Museum, 1400 South Lake Shore Drive, Chicago, IL 60605, telephone (312) 665–7317, email hrobbins@fieldmuseum.org.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Field Museum, Chicago, IL. The human remains and associated funerary objects were removed from Homolovi I and Homolovi II, Navajo County, AZ.

This notice is published as part of the National Park Service’s administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Field Museum professional staff in consultation with representatives of the Hopi Tribe of Arizona and the Zuni Tribe of the Zuni Reservation, New Mexico.

History and Description of the Remains

In 1899, human remains representing, at minimum, 20 individuals were removed from Homolovi I in Navajo County, AZ. The individuals were excavated by J. A. Burt, an employee of the Field Museum, as part of an excavation occurring in the winter of...
1899–1900 sponsored by the Museum. No known individuals were identified. The 24 associated funerary objects are two mugs, three vases, eight bowls, one selenite disc, one circular stone, one stalagmite piece, and eight points. Homolovi I was occupied from around A.D. 1285 to 1390. Based on archeological research, scholarly research, consultation, and museum records, Homolovi I is affiliated with the Hopi Tribe of Arizona and the Zuni Tribe of the Zuni Reservation, New Mexico.

In 1899, human remains representing, at minimum, 33 individuals were removed from Homolovi II in Navajo County, AZ. The individuals were excavated by J. A. Burt, an employee of the Field Museum, as part of an excavation occurring in the winter of 1899–1900 sponsored by the Museum. No known individuals were identified. The 49 associated funerary objects are seven faunal remains, 29 bowls, four awls, one selenite sheet, one bone whistle, one bone bead, one ladle, two water vessels, two jars, and one cloth fragment. Homolovi II was occupied from around A.D. 1350 to 1400. Based on archeological research, scholarly research, consultation, and museum records, Homolovi II is affiliated with the Hopi Tribe of Arizona and the Zuni Tribe of the Zuni Reservation, New Mexico.

In 1899, human remains representing, at minimum, three individuals were removed from Homolovi I or Homolovi II in Navajo County, AZ. The individuals were excavated by J. A. Burt, an employee of the Field Museum, as part of an excavation occurring in the winter of 1899–1900 sponsored by the Museum. No known individuals were identified. No associated funerary objects are present.

Determinations Made by the Field Museum

Officials of the Field Museum have determined that:

• Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 56 individuals of Native American ancestry.
• Pursuant to 25 U.S.C. 3001(3)(A), the 73 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Hopi Tribe of Arizona and the Zuni Tribe of the Zuni Reservation, New Mexico.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Helen Robbins, The Field Museum, 1400 South Lake Shore Drive, Chicago, IL 60605, telephone (312) 665–7317, email hrobbins@fieldmuseum.org, by November 19, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Hopi Tribe of Arizona and the Zuni Tribe of the Zuni Reservation, New Mexico may proceed.

The Field Museum is responsible for notifying the Hopi Tribe of Arizona and the Zuni Tribe of the Zuni Reservation, New Mexico that this notice has been published.

Dated: September 6, 2018.
Melanie O’Brien, Manager, National NAGPRA Program.

DEPARTMENT OF THE INTERIOR
National Park Service
[NPS–WASO–NAGPRA–NPS00026443; PPWOCRADN0–PCU00RP14, RS00000]

Notice of Intent To Repatriate Cultural Items: Fowler Museum at the University of California Los Angeles, Los Angeles, CA
AGENCY: National Park Service, Interior.
ACTION: Notice.

SUMMARY: The Fowler Museum at the University of California Los Angeles (UCLA), in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the Fowler Museum at UCLA. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.
DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Fowler Museum at UCLA at the address in this notice by November 19, 2018.

ADDRESSES: Wendy G. Teeter, Ph.D., Fowler Museum at UCLA, Box 951549, Los Angeles, CA 90095–1549, telephone (310) 825–1864, email wteeter@arts.ucla.edu.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Fowler Museum at UCLA that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service’s administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item(s)

In 1958 and 1959, three cultural items were removed from CA–SDI–525 (W–9) in San Diego County, CA. Carl L. Hubbs, G. Shumway, J. Moriarity, and Claude Warren conducted excavations during the construction of two homes on Scripps Estate Association Lots. The site was dated to the Middle Holocene (between 7,000 and 5,500 B.P.) based on radiocarbon dating. In 1959, the collections were sent to UCLA for curation. 16 burials were uncovered, of which seven were left in situ, two burials (9 and 10) were supposedly sent to UCLA, and the rest were curated with J.R. Moriarty, UC Scripps Institution of Oceanography. Burials 9 and 10 cannot currently be located, although they are reported to have been sent to “Stanford” for dating and despite extensive investigations. Funerary objects were identified in the collections as being removed from these two burials. There were three objects including one stone metate, one shell fragment, and one soil sample. Since the represented burials have not been located these burial items are eligible as NAGPRA unassociated funerary objects.

The site detailed in the paragraphs preceding has been identified through consultation to be within the aboriginal territory of the Kumeyaay people. Based
on archeological evidence, geographic location, ethnographic information, and oral history evidence, these funerary objects are consistent with those of ancestral Kumeyaay people, represented by the Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California; Capitan Grande Band of Diegueno Mission Indians of California (Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California); Ewiiaapaayp Band of Kumeyaay Indians, California; Iipay Nation of Santa Ysabel, California (previously listed as the Santa Ysabel Band of Diegueno Mission Indians of the Santa Ysabel Reservation); Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; San Pasqual Band of Diegueno Mission Indians of California; and Sycuan Band of the Kumeyaay Nation (hereafter referred to as “The Tribes”).

Determinations Made by the Fowler Museum at UCLA

Officials of the Fowler Museum at UCLA have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the three cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Fowler Museum at UCLA for notifying The Tribes that this notice has been published.

Dated: September 6, 2018.
Melanie O’Brien,
Manager, National NAGPRA Program.

FOR FURTHER INFORMATION CONTACT: Jeff Browning, BOEM, Office of Renewable Energy Programs, 45600 Woodland Road, VAM–OREP, Sterling, Virginia 20166, (703) 787–1577 or Jeffrey.Browning@boem.gov.

SUPPLEMENTARY INFORMATION:

Authority: This FSN is published pursuant to subsection 8(p) of the OCS Lands Act (43 U.S.C. 1337(p)), as amended by section 388 of the Energy Policy Act of 2005, and the implementing regulations at 30 CFR part 585, including sections 211 and 216.

Background: BOEM proposed this lease sale on April 11, 2018, in the Atlantic Wind Lease Sale 4A (ATLW–4A) Commercial Leasing for Wind Power on the Outer Continental Shelf Offshore Massachusetts—Final Sale Notice


ACTION: Final Sale Notice for Commercial Leasing for Wind Power on the Outer Continental Shelf Offshore Massachusetts.

SUMMARY: This document is the Final Sale Notice (FSN) for the sale of commercial wind energy leases on the Outer Continental Shelf (OCS) offshore Massachusetts. The Bureau of Ocean Energy Management (BOEM) will offer three leases: Lease OCS–A 0520, Lease OCS–A 0521, and Lease OCS–A 0522 (Lease Areas), which are located within the former Leases OCS–A 0502 and Lease OCS–A 0503 that were unsold during the Atlantic Wind Lease Sale–4 (ATLW–4) on January 29, 2015. BOEM will use an ascending bidding auction format. The FSN contains information pertaining to the areas available for leasing, certain provisions and conditions of the leases, lease details, the lease form, criteria for evaluating competing bids, award procedures, appeal procedures, and lease execution. The issuance of the lease(s) resulting from this sale would not constitute an approval of project-specific plans to develop offshore wind energy. Such plans, if submitted by the lessee, would be subject to subsequent environmental, technical, and public reviews prior to a decision on whether the proposed development should be authorized.

DATES: BOEM will hold a mock auction for the bidders starting at 9:00 a.m. Eastern Standard Time (EST) on December 11, 2018. The monetary auction will be held online and will begin at 9:00 a.m. EST on December 13, 2018. Additional details are provided in the section entitled “Deadlines and Milestones for Bidders.”

Atlantic Wind Lease Sale 4A (ATLW–4A) for Commercial Leasing for Wind Power on the Outer Continental Shelf Offshore Massachusetts—Final Sale Notice

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–2018–0043]

Atlantic Wind Lease Sale 4A (ATLW–4A) for Commercial Leasing for Wind Power on the Outer Continental Shelf Offshore Massachusetts—Final Sale Notice

This document is the Final Sale Notice (FSN) for the sale of commercial wind energy leases on the Outer Continental Shelf (OCS) offshore Massachusetts. The Bureau of Ocean Energy Management (BOEM) will offer three leases: Lease OCS–A 0520, Lease OCS–A 0521, and Lease OCS–A 0522 (Lease Areas), which are located within the former Leases OCS–A 0502 and Lease OCS–A 0503 that were unsold during the Atlantic Wind Lease Sale–4 (ATLW–4) on January 29, 2015. BOEM will use an ascending bidding auction format. The FSN contains information pertaining to the areas available for leasing, certain provisions and conditions of the leases, lease details, the lease form, criteria for evaluating competing bids, award procedures, appeal procedures, and lease execution. The issuance of the lease(s) resulting from this sale would not constitute an approval of project-specific plans to develop offshore wind energy. Such plans, if submitted by the lessee, would be subject to subsequent environmental, technical, and public reviews prior to a decision on whether the proposed development should be authorized.

DATES: BOEM will hold a mock auction for the bidders starting at 9:00 a.m. Eastern Standard Time (EST) on December 11, 2018. The monetary auction will be held online and will begin at 9:00 a.m. EST on December 13, 2018. Additional details are provided in

the section entitled “Deadlines and Milestones for Bidders.”

FOR FURTHER INFORMATION CONTACT: Jeff Browning, BOEM, Office of Renewable Energy Programs, 45600 Woodland Road, VAM–OREP, Sterling, Virginia 20166, (703) 787–1577 or Jeffrey.Browning@boem.gov.

SUPPLEMENTARY INFORMATION:

Authority: This FSN is published pursuant to subsection 8(p) of the OCS Lands Act (43 U.S.C. 1337(p)), as amended by section 388 of the Energy Policy Act of 2005, and the implementing regulations at 30 CFR part 585, including sections 211 and 216.

Background: BOEM proposed this lease sale on April 11, 2018, in the Atlantic Wind Lease Sale 4A (ATLW–4A) Commercial Leasing for Wind Power on the Outer Continental Shelf Offshore Massachusetts—Proposed Sale Notice (PSN), which was published in the Federal Register (83 FR 15618). A 60-day comment period followed. BOEM received 21 comment submissions in response to the PSN, which are available on regulations.gov (Docket ID: BOEM–2018–0016) at: https://www.regulations.gov/docket?D=BOEM-2018–0016. BOEM has posted its responses to comments submitted during the PSN comment period. The document, entitled Response to Comments, can be found through BOEM’s website at: https://www.boem.gov/Commercial-Wind-Leasing/Massachusetts/Lease-Sale-4A/.

In response to the PSN, BOEM received new qualification materials from thirteen entities that BOEM has determined to be qualified to participate in this sale, and four affirmations of interest from entities that were qualified to participate in the first Massachusetts Lease Sale (ATLW–4) in January of 2015. In addition, the two entities that submitted unsolicited lease requests for the Lease Areas have also qualified, resulting in a total of 19 qualified entities.

BOEM made several changes from the description of the lease sale format and leases that were published in the PSN. The primary changes are: The lease sale no longer contains a non-monetary bidding credit, and will instead use a straight ascending bid format; the two proposed lease areas have been re-divided into three Lease Areas; each lease now contains conditions related to vessel transit corridors and setbacks between adjacent leases; and the operations term of each lease has been extended from 25 years to 33 years.

List of Eligible Bidders: BOEM has determined that the following entities are legally, technically, and financially
qualified to hold a commercial wind
lease offshore Massachusetts pursuant
to 30 CFR 585.106 and 107, and
therefore may participate in this lease
sale as bidders subject to meeting the
requirements outlined in this notice:

<table>
<thead>
<tr>
<th>Company name</th>
<th>Company No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avangrid Renewables, LLC</td>
<td>15019</td>
</tr>
<tr>
<td>Camellia Wind Energy LLC</td>
<td>15077</td>
</tr>
<tr>
<td>CI II Blue Cloud Wind Energy II LLC</td>
<td>15079</td>
</tr>
<tr>
<td>Cobra Industrial Services, Inc</td>
<td>15073</td>
</tr>
<tr>
<td>Deepwater Wind New England, LLC</td>
<td>15071</td>
</tr>
<tr>
<td>East Wind LLC</td>
<td>15012</td>
</tr>
<tr>
<td>EC&amp;R Development, LLC</td>
<td>15076</td>
</tr>
<tr>
<td>EDF Renewables Development, Inc</td>
<td>15080</td>
</tr>
<tr>
<td>EDPP Offshore North America LLC</td>
<td>15027</td>
</tr>
<tr>
<td>Enbridge Holdings (Green Energy) LLC</td>
<td>15065</td>
</tr>
<tr>
<td>Innogy US Renewable Projects LLC</td>
<td>15061</td>
</tr>
<tr>
<td>Mayflower Wind Energy LLC</td>
<td>15082</td>
</tr>
<tr>
<td>Northeast Wind Energy LLC</td>
<td>15078</td>
</tr>
<tr>
<td>Northland Power America Inc</td>
<td>15068</td>
</tr>
<tr>
<td>PNE WIND USA, Inc</td>
<td>15056</td>
</tr>
<tr>
<td>Equinor Wind US LLC</td>
<td>15058</td>
</tr>
<tr>
<td>Vineyard Wind LLC</td>
<td>15010</td>
</tr>
<tr>
<td>Wind Future LLC</td>
<td>15067</td>
</tr>
<tr>
<td>wpd offshore Alpha LLC</td>
<td>15060</td>
</tr>
</tbody>
</table>

**Affiliated Entities:** On the Bidder’s Financial Form (BFF) discussed below, eligible bidders must list any eligible bidders with whom they are affiliated. Affiliated eligible bidders are not permitted to compete against each other in the lease sale, and must decide by the start of the auction which eligible bidder (if any) will participate. If two or more affiliated bidders participate in the auction, BOEM may disqualify some or all such bidders from the auction.

BOEM considers two entities to be affiliated if (a) one entity (or its parent or subsidiary) has or retains any right, title, or interest in the other entity (or its parent or subsidiary), including any ability to control or direct actions with respect to such entity, either directly or indirectly, individually or through any other party; or (b) the entities are both direct or indirect subsidiaries of the same parent company.

**Deadlines and Milestones for Bidders:**
This section describes the major deadlines and milestones in the auction process from publication of this FSN to execution of the lease pursuant to this sale. These are organized into various stages: The FSN Waiting Period; Conducting the Auction; and From the Auction to Lease Execution.

**FSN Waiting Period**
- **Bidder’s Financial Form:** Each bidder must submit a BFF to BOEM in order to participate in the auction.

BOEM must receive each bidder’s BFF no later than November 2, 2018. BOEM will consider extensions to this deadline only if BOEM determines that the failure to timely submit a BFF was caused by events beyond the bidder’s control. The BFF can be downloaded at: https://www.boem.gov/Commercial-Wind-Leasing/Massachusetts/Lease-Sale-4A/. Once BOEM has processed a bidder’s BFF, the bidder may log into pay.gov and submit a bid deposit.

For purposes of this auction, BOEM will not consider any BFFs submitted by bidders for previous lease sales. BOEM will only accept an originally executed paper copy of the BFF. The BFF must be executed by an authorized representative listed on the bidder’s legal qualifications. Each bidder is required to sign the self-certification in the BFF, in accordance with 18 U.S.C. 1001 (Fraud and False Statements).

**Conduct the Auction**
- **Mock Auction:** BOEM will hold a Mock Auction on December 11, 2018 beginning at 9:00 a.m. EST. The Mock Auction will be held online. BOEM will contact each bidder that has timely filed a BFF and bid deposit and provide instructions for participation. Only bidders that have timely submitted BFFs and bid deposits will be permitted to participate in the Mock Auction.

**Monetary Auction:** On December 13, 2018, BOEM, through its contractor, will hold the auction. The first round of the auction will start at 9:00 a.m. EST. The auction will proceed electronically according to a schedule to be distributed by the BOEM Auction Manager at the time of the auction. BOEM anticipates that the auction will last one business day, but it may continue on consecutive business days, as necessary, until the auction ends in accordance with the procedures described in the “Auction Procedures” section of this notice.

**Announce Provisional Winners:**
BOEM will announce the provisional winners of the lease sale after the auction ends.

**From the Auction to Lease Execution**
- **Refund Non-Winners:** Once the provisional winners have been announced, BOEM will provide the non-winners a written explanation of why they did not win and return their bid deposits.

**Department of Justice (DOJ) Review:**
DOJ will have 30 days in which to conduct an antitrust review of the auction, pursuant to 43 U.S.C. 1337(c).

**Delivery of the Lease:** BOEM will send three lease copies to each winner, with instructions on how to execute the lease. The first year’s rent is due 45 calendar days after the winners receive the lease copies for execution.

**Return the Lease:** Within 10 business days of receiving the lease copies, the auction winners must post financial assurance, pay any outstanding balance of their bonus bids (i.e., winning monetary bid minus applicable bid deposit), and sign and return the three executed lease copies.

The winners may request extensions to the 10-day deadline, and BOEM may grant such extensions if BOEM determines the delay to be caused by events beyond the requesting winner’s control, pursuant to 30 CFR 585.224(e).

**Execution of Lease:** Once BOEM has received the signed lease copies and verified that all other required materials have been received, BOEM will make a final determination regarding its issuance of the leases and will execute the leases, if appropriate.

**Area Offered for Leasing:**
The area available for sale will be auctioned as three leases: Lease OCS–A 0520, Lease OCS–A 0521, and Lease OCS–A 0522. Lease OCS–A 0520 consists of 128,811 acres, Lease OCS–A 0521 consists of 127,388 acres, and Lease OCS–A 0522 consists of 132,370 acres. These Lease Areas lie within the same area that BOEM announced on April 11, 2018 and published in the PSN. In response to comments received on the PSN, however, BOEM re-divided the available area into three leases.

**Map of the Area Offered for Leasing:**
A map of the Lease Areas, and GIS spatial files X, Y (eastings, northings) UTM Zone 18, NAD83 Datum, and geographic X, Y (longitude, latitude), NAD83 Datum can be found on BOEM’s website at: https://www.boem.gov/Commercial-Wind-Leasing/Massachusetts/Lease-Sale-4A/.

A large scale map of the Lease Areas, showing boundaries of the area with numbered blocks, is available from BOEM upon request at the following address: Bureau of Ocean Energy Management, Office of Renewable Energy Programs, 45600 Woodland
Road, VAM–OREP, Sterling, Virginia 20166, Phone: (703) 787–1300, Fax: (703) 787–1708.

Environmental Reviews and Lease Stipulations: The PSN explains that the existing June 2014 Revised Massachusetts Environmental Assessment (EA) and associated consultations adequately assess the reasonably foreseeable environmental effects of the issuance of commercial leases and associated site characterization activity in the Massachusetts Wind Energy Area (WEA), which includes the areas that BOEM will lease pursuant to this FSN. Although this FSN represents a change in the number and size of the leases to be sold compared to the PSN, the scope of activities anticipated as a result of the lease sale still falls within the range analyzed in the EA because, among other things, those leases still fall within the boundaries of former Leases OCS–A 0502 and OCS–A 0503. BOEM will conduct additional environmental reviews upon receipt of a lessee’s proposed project-specific plans, such as a Site Assessment Plan (SAP) or Construction and Operations Plan (COP). As conditions of plan approval, Lessees may be required to contribute to regional environmental monitoring programs that are presently being developed jointly between state and Federal authorities and stakeholder groups. For Lease OCS–A 0522, BOEM may require terms and conditions of project approval aimed at mitigating, minimizing, or avoiding impacts to sea ducks. Due to the development of the Massachusetts WEA, BOEM took steps to protect sea ducks (among other species) by removing lease blocks. Recent information suggests that high concentrations of sea ducks may forage in the easternmost lease blocks (6251, 6252, & 6302) during the winter months. BOEM is also adding additional lease stipulations that were not contained in the leases offered in ATLW–4.

Fisheries Communication Plan: In order to facilitate interactions between lessees and commercial fisheries and maintain consistency with its most recent lease sale, BOEM is once again including a lease stipulation to ensure the Lessee coordinates and communicates with commercial and recreational fishermen. BOEM has determined that this stipulation is prudent for the leases in this sale, given the importance of fishing to the economies of Southern New England states. The lease stipulation states as follows: Fisheries Communications Plan (FCP) and Fisheries Liaison. The Lessee must develop a publicly available FCP that describes the strategies that the Lessee intends to use for communicating with fisheries stakeholders prior to and during activities in support of the submission of a plan. The FCP must include the contact information for an individual retained by the Lessee as its primary point of contact with fisheries stakeholders (i.e., Fisheries Liaison). If the Lessee does not develop a project website, the FCP must be made available to the Lessor and the public upon request.

Best Available Technologies for Meteorological Buoys: BOEM has included a lease stipulation aimed at requiring the Lessee to use best available technologies in designs for meteorological buoys and other similar floating devices to ensure entanglement risks to marine protected species are minimized to discountable levels. Although this is a new lease stipulation, it is intended to provide clarification for existing buoy requirements contained in the 2013 Biological Opinion issued to BOEM by NOAA for Commercial Wind Lease Issuance and Site Assessment Activities on the Atlantic Outer Continental Shelf in Massachusetts, Rhode Island, New York and New Jersey Wind Energy and discussed in the 2014 EA. The lease stipulation states as follows: The Lessee must ensure that any structures or devices attached to the seafloor for continuous periods greater than 24 hours use the best available mooring systems for minimizing the risk of entanglement or entrapment of marine mammals, manatees, and marine turtles. The best available mooring system may include, but is not limited to, vertical and floating lines (chains, cables, or coated rope systems), swivels, shackles, and anchor designs. All mooring lines and ancillary attachment lines must use one or more of the following measures to reduce entanglement risk: shortest practicable line length, rubber sleeves, weak-links, chains, cables or similar equipment, or types that prevent lines from looping or wrapping around animals, or entrapping protected species. Any equipment must be attached by a line within a rubber sleeve for rigidity. The length of the line must be as short as necessary to meet its intended purpose. If an entangled live or dead marine protected species is reported, the Lessee must provide any assistance to authorized stranding response personnel as requested by BOEM or NMFS.

Vessel Transit Corridors: Fishermen have requested that offshore wind facilities be designed in a manner that, among other things, provides for safe transit through the facility to fishing grounds. Current BOEM leaseholders offshore Rhode Island and Massachusetts (Leases OCS–A 0486, OCS–A 0487, OCS–A 0500, and OCS–A 0501) are presently working with stakeholders, and the United States Coast Guard to identify those transit routes and establish corridors in their lease submittals. BOEM has determined that such corridors are only effective if they continue, as appropriate, through the Lease Areas. As such, BOEM has added the following lease term:

In its COP project design, Lessee must extend any BOEM-approved vessel transit corridors in adjacent lease areas, unless BOEM determines that such corridors are not necessary or can be modified. Lessee may not construct any surface structures in such vessel transit corridors.

Surface Structure Setback: In response to comments received on the PSN, BOEM will require lessees to incorporate a setback of 750 meters (m) from any shared lease boundary into future COP submittals, unless both adjacent lessees agree to a decreased setback. The 750 m setback for each lease results in a minimum distance of 1,500 m between turbine locations of adjacent leases. BOEM has added a term setting forth this obligation in Addendum A of Leases OCS–A 0520, OCS–A 0521, and OCS–A 0522 which reads as follows: In its COP project design, the Lessee must incorporate a 750 m setback from any shared lease boundary within which the Lessee may not construct any surface structures, unless the Lessee and the adjacent lessee agree to a smaller setback, the Lessee submits such agreement to BOEM, and BOEM approves it.

 Withdrawal of Blocks: BOEM reserves the right to withdraw all or portions of the Lease Areas prior to executing the leases with the winning bidders. Lease Terms and Conditions: BOEM has included terms, conditions, and stipulations for the OCS commercial wind leases to be offered through this sale. After the leases are issued, BOEM reserves the right to require compliance with additional terms and conditions associated with approval of a SAP or COP. The leases are available on BOEM’s website at: http://www.boem.gov/Commercial-Wind-Leasing/MassachusettsLease-Sale-4A/. The leases include the following seven attachments:

- Addendum “A” (Description of Leased Area and Lease Activities);
The lessee must also pay rent for any project easement associated with the lease, commencing on the date that BOEM approves the COP (or modification thereof) that describes the project easement. Annual rent for a project easement that is 200 feet wide and centered on the transmission cable is $70 per statute mile. For any additional acreage required, the lessee must also pay the greater of $5 per acre per year or $450 per year.

Operating Fee: For purposes of calculating the initial annual operating fee payment pursuant to 30 CFR 585.506, BOEM applies an operating fee rate to a proxy for the wholesale market value of the electricity expected to be generated from the project during its first twelve months of operations. This initial payment will be prorated to reflect the period between the commencement of commercial operations and the Lease Anniversary. The subsequent annual operating fee payment is due within 45 days of the commencement of commercial operations. Thereafter, subsequent annual operating fee payments are due on or before each Lease Anniversary.

The subsequent annual operating fee payments are calculated by multiplying the operating fee rate by the imputed wholesale market value of the projected annual electric power production. For the purposes of this calculation, the imputed market value is the product of the project’s annual nameplate capacity, the total number of hours in the year (8,760), the capacity factor, and the annual average price of electricity derived from a historical regional wholesale power price index. For example, the annual operating fee for an 800 MW wind facility operating at a 40% capacity (i.e., capacity factor of 0.4) with a regional wholesale power price of $40/MWh and an operating fee rate of 0.02 would be calculated as follows:

\[
\text{Annual Operating Fee} = 800 \text{MW} \times 8,760 \text{ hrs/year} \times 0.4 \times \frac{\$40}{\text{MWh}} \times 0.02 = \$2,242,560
\]

Operating Fee Rate: The operating fee rate is the share of imputed wholesale market value of the projected annual electric power production due to the Office of Natural Resources Revenue as an annual operating fee. For the Lease Areas, BOEM will set the fee rate at 0.02 (i.e., 2%) for the entire life of commercial operations.

Nameplate Capacity: Nameplate capacity is the maximum rated electric output, expressed in MW, which the turbines of the wind facility under commercial operations can produce at their rated wind speed as designated by the turbine’s manufacturer. The lessee will specify in its COP the nameplate capacity available at the start of each year of commercial operations on the lease. For example, if the lessee specifies 100 turbines in its COP, and each is rated by the manufacturer at 8 MW, the nameplate capacity of the wind facility is 800 MW.

Capacity Factor: The capacity factor relates to the amount of energy delivered to the grid during a period of time compared to the amount of energy the wind facility would have produced at full capacity during that same period of time. This factor is represented as a decimal between zero and one. There are several reasons why the amount of power delivered is less than the theoretical 100% of capacity. For a wind facility, the capacity factor is mostly...
determined by the availability of wind. Transmission line loss and down time for maintenance or other purposes also affect the capacity factor.

The capacity factor for the year in which the Commercial Operation Date occurs, and for the first six full years of commercial operations on the lease, is set to 0.4 (i.e., 40%). At the end of the sixth year, the capacity factor may be adjusted to reflect the performance over the previous five years based upon the actual metered electricity generation at the delivery point to the electrical grid. Similar adjustments to the capacity factor may be made once every five years thereafter. The maximum change in the capacity factor from one period to the next will be limited to plus or minus 10% of the previous period’s value.

Wholesale Power Price Index: Pursuant to 30 CFR 585.506(c)(2)(i), the wholesale power price, expressed in dollars per MW-hour, is determined at the time each annual operating fee payment is due, based on the weighted average of the inflation-adjusted peak and off-peak spot price indices for the Northeast—Massachusetts Hub for the most recent year of spot price data available. The wholesale power price is adjusted for inflation from the year associated with the published spot price indices to the year in which the operating fee is due, based on the Lease Anniversary and using annual implicit price deflators as reported by the U.S. Department of Commerce, Bureau of Economic Analysis.

Financial Assurance: Within 10 business days after receiving the lease copies and pursuant to 30 CFR 585.515–516, the provisional winners of the leases must provide an initial lease-specific bond or other approved means of meeting the lessor’s initial financial assurance requirements, in the amount of $100,000. The provisional winners may meet financial assurance requirements by posting a surety bond or by setting up an escrow account with a trust agreement giving BOEM the right to withdraw the money held in the account on demand. BOEM encourages the provisionally winning bidder to discuss the financial assurance requirement with BOEM as soon as possible after the auction has concluded.

BOEM will base the amount of all SAP, COP, and decommissioning financial assurance on cost estimates for meeting all accrued lease obligations at the respective stages of development. The required amount of supplemental and decommissioning financial assurance will be determined on a case-by-case basis.

The financial terms described above can be found in Addendum “B” of the leases, which BOEM has made available with this notice on its website at: https://www.boem.gov/Commercial-Wind-Leasing/Massachusetts/Lease-Sale-4A/.

Bidder’s Financial Form: Each bidder must fill out the BFF referenced in this FSN. BOEM has also made a copy of the form available with this notice on its website at: https://www.boem.gov/Commercial-Wind-Leasing/Massachusetts/Lease-Sale-4A/. BOEM recommends that each bidder designate an email address in its BFF that the bidder will then use to create an account in pay.gov (if it has not already done so).

BOEM will not consider BFFs submitted by bidders for previous lease sales to satisfy the requirements of this auction. BOEM will also only consider BFFs submitted after the deadline (November 2, 2018) if BOEM determines that the failure to timely submit the BFF was caused by events beyond the bidder’s control. BOEM will only accept an original, executed paper copy of the BFF. The BFF must be executed by an authorized representative listed in the qualifications package on file with BOEM as authorized to bind the company.

Bid Deposit: A bid deposit is an advance cash payment submitted to BOEM in order to participate in the auction. After creating an account in pay.gov (if necessary), bidders may use the Bid Deposit Form on the pay.gov website to leave a deposit. Each bidder must submit a bid deposit of $450,000 no later than November 16, 2018. Any bidder who fails to submit the bid deposit by this deadline may be disqualified from participating in the auction.

Following the auction, bid deposits will be applied against bonus bids or other obligations owed to BOEM. If the bid deposit exceeds a bidder’s total financial obligation, BOEM will refund the balance of the bid deposit to the bidder. BOEM will refund bid deposits to non-winners once BOEM has announced the provisional winner.

If BOEM offers a lease pursuant to a provisionally winning bid, and that bidder fails to timely return the signed lease form, establish financial assurance, and/or pay the balance of its bid, BOEM will retain the bidder’s $450,000 bid deposit. In such a circumstance, BOEM reserves the right to determine which bid would have won in the absence of the bid and previously-determined to be the winning bid, and to offer a lease pursuant to this next highest bid.

Minimum Bid: The minimum bid is the lowest bid BOEM will accept as a winning bid, and it is where BOEM will start the bidding in the auction. BOEM has established a minimum bid of $2.00 per acre for this lease sale.

Auction Procedures

Ascending Bidding With Cash Bid Variable

As authorized under 30 CFR 585.220(a)(2) and 585.221(a)(1), BOEM will use an ascending bidding auction with cash as the bid variable for this lease sale. BOEM will start the auction using the minimum bid prices for each lease area, and increase those prices incrementally until no more than one active bidder per lease area remains in the auction.

The Auction

Using an online bidding system to host the auction, BOEM will start the bidding for Lease OCS–A 0520 at $257,622, Lease OCS–A 0521 at $254,776, and for Lease OCS–A 0522 at $264,740. Each bidder may bid on only one lease area at a time, and can win at most one of the three Lease Areas offered in this sale.

The auction will be conducted in a series of rounds. At the start of each round, BOEM will state an asking price for each lease area. If a bidder is willing to meet the asking price for one of the lease areas, it will indicate its intent by submitting a bid equal to the asking price. A bid at the full asking price is referred to as a “live bid.” To participate in the next round of the auction, a bidder must submit a live bid for one of the lease areas in each previous round. As long as there are two or more live bids for at least one lease area, the auction moves to the next round. BOEM will raise the asking price for each lease area that has received two or more live bids in the previous round. Asking price increments will be determined based on several factors, including (but not necessarily limited to) the expected time needed to conduct the auction, and the number of rounds that have already occurred. BOEM reserves the right to increase or decrease bidding increments as appropriate.

Generally, a bidder that submitted a live bid in the previous round is free to bid on any of the three areas in the current round. However, there is an exception. A bidder may switch its live bid from one lease area to another in the current round only if its bid from the previous round was contested—e.g., a bidder cannot switch from OCS–A 0520 to OCS–A 0521 unless there was at least one other live bid for OCS–A 0520 in
the last round. If the bid was not contested in the previous round, the bidder cannot switch lease areas, and its previous round bid will be carried forward to the next round. If another bidder places a live bid on OCS-A 0520 later in the auction, BOEM will stop automatically carrying forward the previously uncontested bid on that lease area. The bidder that placed the previously carried forward bid is then free to bid on that lease area or either of the other two lease areas in the next round at the new asking prices. A bidder remains eligible to participate in the auction if it submitted a live bid in the prior round, or had a previously uncontested live bid carried forward by BOEM to the current round. If a bidder decides to stop bidding further when its bid is contested, there are still circumstances in which the bidder could win (e.g., if the winning bid is disqualified at the award stage of the auction). If this happens, the bidder may be bound by its bid and thus obligated to pay the full bid amount. Bidders may be bound by any of their bids until the auction results are finalized.

Between rounds, BOEM will disclose to all bidders that submitted bids in the first round of the auction: (1) The number of live bids (including bids carried forward) for each lease area in the previous round of the auction (i.e., the level of demand); and (2) the asking price for each lease area in the upcoming round of the auction.

A bidder is only eligible to continue bidding in the auction if it has submitted a live bid (or had a bid carried forward) in the previous round. In any round after the first round, however, a bidder may submit an “exit bid” (also known as an “intra-round bid”). An exit bid is a bid that is higher than the previous round’s asking price, submitted for the same lease area as the bidder’s contested live bid in the previous round, but less than the current round’s asking price. An exit bid is not a live bid, and it represents the final bid that a bidder may submit in the auction. During the auction, the exit bid can only be seen by BOEM, and not by other bidders.

A lease area with only exit bids in a given round will not have its asking price raised in the next round, since BOEM only raises asking prices when a lease area receives multiple live bids. As soon as all three Lease Areas have one or zero live bids (including bids carried forward), the auction is over, regardless of the number of exit bids on each area.

After the bidding ends, BOEM will determine the provisionally winning bids for each lease area. The provisionally winning bid for a lease area will be the highest bid (live bid or exit bid) received for that lease area, except that no bidder may win more than one lease area. The award procedures described here could result in a tie, for example if two bidders submit identical high exit bids. In such cases, BOEM would resolve the tie by randomized means subject to the constraint of no bidder winning more than one lease area. After the last round of the auction, there will be a listing of all scenarios that would generate the same maximum revenue. This can include multiple ties. Each of those scenarios is given an equal probability of winning. The selection of the winning scenario is determined by pseudorandom numbers.

Provisional winners may be disqualified if they are subsequently found to have violated auction rules or BOEM regulations, or otherwise engaged in conduct detrimental to the integrity of the competitive auction. If a bidder submits a bid that BOEM determines to be a provisionally winning bid, the bidder will be expected to sign the applicable lease documents, establish financial assurance, and submit the cash balance of its bid (i.e., winning bid amount minus the bid deposit) within 10 business days of receiving the lease copies, pursuant to 30 CFR 585.224. BOEM reserves the right not to issue the lease to the provisionally winning bidder if that bidder fails to timely sign and pay for the lease or otherwise comply with applicable regulations or the terms of the FSN. In that case, the bidder would forfeit its bid deposit. BOEM may consider failure of a bidder to timely pay the full amount due to be an indication that the bidder may no longer be financially qualified to participate in other lease sales under 30 CFR 585.106 and 585.107.

Additional Information Regarding the Auction Format

Bidder Authentication

For the online auction, BOEM will require two-factor authentication. After BOEM has processed the bid deposits, the auction contractor sends several bidder authentication packages to the bidders. One package will contain digital authentication tokens needed to allow access to the auction website. As a general practice, tokens are mailed to the Primary Point of Contact indicated on the BFF. This individual is responsible for distributing the tokens to the individuals authorized to bid for that company. Bidders are to ensure that each token is activated within three business days following the auction. An addressed, stamped envelope will be provided to facilitate this process. In the event that a bidder fails to submit a bid deposit or does not participate in the auction, BOEM will de-activate that bidder’s tokens and login information, and the bidder will be asked to return its tokens. Under certain circumstances (for example, if the authorized bidders are geographically dispersed and the ability for the Primary Point of Contact to timely distribute the materials is in question), BOEM may send all materials directly to the authorized bidders instead of sending to the Primary Point of Contact.

The second package contains login credentials for authorized bidders. The login credentials are mailed to the address provided in the BFF for each authorized individual. Bidders can confirm these addresses by calling 703–787–1320. This package will contain user login information and instructions for accessing the Bidder Manual for the auction system, the Auction System Technical Supplement (ASTS) and the Alternative Bidding Form, all of which are available on BOEM’s website at: https://www.boem.gov/Commercial-Wind-Leasing/Massachusetts/Lease-Sale-4A/. The login information, along with the tokens, will be tested during the Mock Auction.

Timing of Auction

The auction will begin at 9:00 a.m. EST on December 13, 2018. Bidders may log in as early as 8:30 a.m. on that day. We recommend that bidders log in earlier than 9:00 a.m. on that day to ensure that any login issues are resolved prior to the start of the auction. Once bidders have logged in, they should review the auction schedule, which lists the anticipated start times, end times, and recess times of each round in the auction. Each round is structured as follows:

- Round bidding begins;
- Bidders enter their bids;
- Round bidding ends and the Recess begins;
- During the Recess, previous Round results and next round asking prices are posted;
- Bidders review the previous Round results and prepare their next Round bids; and
- Next Round bidding begins.

The first round will last about 30 minutes, though subsequent rounds may be shorter. Recesses are anticipated to last approximately 10 minutes. The description of the auction schedule included with this FSN is tentative. Bidders should consult the auction schedule on the bidding website during the auction for updated times. Bidding will continue until about 6:00 p.m. EST.
each day. BOEM anticipates that the auction will last one business day, but may be extended for additional business days as necessary until the auction is complete.

BOEM and the auction contractors will use the auction platform messaging service to keep bidders informed on issues of interest during the auction. For example, BOEM may change the schedule at any time, including during the auction. If BOEM changes the schedule during an auction, it will use the messaging feature to notify bidders that a revision has been made, and will direct bidders to the relevant page. BOEM will also use the messaging system for other updates during the auction.

Bidders may place bids at any time during the round. At the top of the bidding page, a countdown clock shows how much time remains in the round. Bidders have until the scheduled time to place bids. Bidders should do so according to the procedures described in this notice, and the ASTS. Information about the round results will only be made available after the round has closed, so there is no strategic advantage to placing bids early or late in the round.

The ASTS will elaborate on the auction procedures described in this FSN. In the event of an inconsistency between the ASTS and the FSN, the FSN is controlling.

Prohibition on Communications Between Bidders During Auction

During the auction, bidders are prohibited from communicating with each other regarding their participation in the auction. Also during the auction, bidders are prohibited from communicating to the general public regarding any aspect of their participation or lack thereof in the auction, including, but not limited to, through social media, updated websites, or press releases.

Alternate Bidding Procedures

Alternate Bidding Procedures enable a bidder who is having difficulty accessing the internet to submit its bid via fax using an Alternate Bidding Form available on BOEM’s website at: https://www.boem.gov/Commercial-Wind-Leasing/Massachusetts/Lease-Sale-4A/.

In order to be authorized to use an Alternate Bidding Form, a bidder must call the help desk number listed in the Auction Manual before the end of the round. BOEM will authenticate the caller to ensure he/she is authorized to bid on behalf of the bidder. The bidder must explain the reasons for which he/she is forced to place a bid using the Alternate Bidding Procedures. BOEM may, in its sole discretion, permit or refuse to accept a request for the placement of a bid using the Alternate Bidding Procedures.

Rejection or Non-Acceptance of Bids: BOEM reserves the right and authority to reject any and all bids that do not satisfy the requirements and rules of the auction, the FSN, or applicable regulations and statutes.

Anti-Competitive Review: Bidding behavior in this sale is subject to Federal antitrust laws. Accordingly, following the auction, but before the acceptance of bids and the issuance of leases, BOEM will “allow the Attorney General, in consultation with the Federal Trade Commission, 30 days to review the results of the lease sale.” 43 U.S.C. 1337(c). If a provisionally winning bidder is found to have engaged in anti-competitive behavior in connection with its participation in the competitive bidding process, BOEM may reject its provisionally winning bid. Compliance with BOEM’s auction procedures and regulations is not an absolute defense to violations of antitrust laws.

Anti-competitive behavior determinations are fact-specific. However, such behavior may manifest itself in several different ways, including, but not limited to:

• An express or tacit agreement among bidders not to bid in an auction, or to bid a particular price;
• An agreement among bidders not to bid;
• An agreement among bidders not to bid against each other; or
• Other agreements among bidders that have the potential to affect the final auction price.

BOEM will decline to award a lease pursuant to 43 U.S.C. 1337(c) if the Attorney General, in consultation with the Federal Trade Commission, determines that awarding the lease would be inconsistent with the antitrust laws.

For more information on whether specific communications or agreements could constitute a violation of Federal antitrust law, please see https://www.justice.gov/atr/business-resources or consult legal counsel.

Process for Issuing the Lease: Once all post-auction reviews have been completed to BOEM’s satisfaction, BOEM will issue three unsigned copies of the lease to each provisionally winning bidder. Within 10 business days after receiving the lease copies, the provisionally winning bidders must:

1. Sign and return the lease copies on the bidder’s behalf;
2. File financial assurance, as required under 30 CFR 585.515–537; and
3. Pay by electronic funds transfer (EFT) the balance (if any) of the bonus bid (winning bid less the bid deposit). BOEM requires bidders to use EFT procedures (not pay.gov, the website bidders used to submit bid deposits) for payment of the balance of the bonus bid, following the detailed instructions contained in the “Instructions for Making Electronic Payments” available on BOEM’s website at: https://www.boem.gov/Commercial-Wind-Leasing/Massachusetts/Lease-Sale-4A/.

BOEM will not execute a lease until the three requirements above have been satisfied, BOEM has accepted the provisionally winning bidder’s financial assurance pursuant to 30 CFR 585.515, and BOEM has processed the provisionally winning bidder’s payment.

BOEM may extend the 10 business day deadline for signing a lease, filing the required financial assurance and/or paying the balance of the bonus bid if BOEM determines the delay was caused by events beyond the provisionally winning bidder’s control.

If a provisionally winning bidder does not meet these requirements or otherwise fails to comply with applicable regulations or the terms of the FSN, BOEM reserves the right not to issue the lease to that bidder. In such a case, the provisionally winning bidder will forfeit its bid deposit. Also in such a case, BOEM reserves the right to identify the next highest bidder for that lease area submitted during the lease sale by a bidder who has not won one of the other lease areas, and to offer the lease to that bidder pursuant to its bid. Within 45 calendar days of the date that a provisionally winning bidder receives copies of the lease, it must pay the first year’s rent using the pay.gov Renewable Energy Initial Rental Payment form available at: https://www.pay.gov/public/form/start/27797604/.

Subsequent annual rent payments must be made following the detailed instructions contained in the “Instructions for Making Electronic Payments,” available on BOEM’s website at: https://www.boem.gov/Commercial-Wind-Leasing/Massachusetts/Lease-Sale-4A/.

Non-Procurement Debarment and Suspension Regulations: Pursuant to regulations at 43 CFR part 42, subpart C, an OCS renewable energy lessee must comply with the Department of the Interior’s non-procurement debarment and suspension requirements under 45 CFR 180 and 1400. The lessee must also communicate this requirement to
persona with whom the lessee does business relating to this lease, by including this term as a condition in their contracts and other transactions.

**Force Majeure:** The Program Manager of BOEM’s Office of Renewable Energy Programs has the discretion to change any auction details specified in the FSN, including the date and time, in case of a force majeure event that the Program Manager deems may interfere with a fair and proper lease sale process. Such events may include, but are not limited to: Natural disasters (e.g., earthquakes, hurricanes, floods, blizzards), wars, riots, acts of terrorism, fire, strikes, civil disorder or other events of a similar nature. In case of such events, BOEM will notify all qualified bidders via email, phone, or through the BOEM website at: http://www.boem.gov/Renewable-Energy-Program/index.aspx. Bidders should call 703–787–1320 if they have concerns.

**Appeals:** The appeals procedures are provided in BOEM’s regulations at 30 CFR 585.225 and 585.118(c). Pursuant to 30 CFR 585.225:

(a) If BOEM rejects your bid, BOEM will provide a written statement of the reasons and refund any money deposited with your bid, without interest.

(b) You will then be able to ask the BOEM Director for reconsideration, in writing, within 15 business days of bid rejection, under 30 CFR 585.118(c)(1). We will send you a written response either affirming or reversing the rejection.

The procedures for appealing final decisions with respect to lease sales are described in 30 CFR 585.118(c).

**Protection of Privileged or Confidential Information:** BOEM will protect privileged or confidential information that you submit, as required by the Freedom of Information Act (FOIA). Exemption 4 of FOIA applies to “trade secrets and commercial or financial information that you submit that is privileged or confidential.” 5 U.S.C. 552(b)(4).

If you wish to protect the confidentiality of such information, clearly mark it “Contains Privileged or Confidential Information” and consider submitting such information as a separate attachment. BOEM will not disclose such information, except as required by FOIA. Information that is not labeled as privileged or confidential may be regarded by BOEM as suitable for public release. Further, BOEM will not treat aggregate summaries of otherwise confidential information.

**Departments:**

**DEPARTMENT OF THE INTERIOR**

Bureau of Ocean Energy Management

**[Docket No. BOEM–2018–0045]**

**Commercial Leasing for Wind Power Development on the Outer Continental Shelf (OCS) Offshore California—Call for Information and Nominations (Call)**

**AGENCY:** Bureau of Ocean Energy Management, Interior.

**ACTION:** Call for Information and Nominations (hereinafter referred to as “Call” or “notice”) for Commercial Leasing for Wind Power Development on the OCS offshore California.

**SUMMARY:** The Bureau of Ocean Energy Management (BOEM) invites the submission of information and nominations for commercial wind leases that would allow a lessee to propose the construction of a wind energy project on the OCS offshore California, and to develop one or more projects, if approved, after further environmental review. This is not a leasing announcement, but the Call Areas or portions of Call Areas described may be available for future leasing. BOEM will use responses to this Call to gauge specific interest in acquiring commercial wind leases in some or all of the Call Areas. Any nominations submitted in response to this Call should provide detailed and specific information addressing the requirements described in the section of this notice entitled, “Required Nomination Information.”

This Call also requests comments and information regarding site conditions, resources, and multiple uses in close proximity to, or within, the Call Areas that would be relevant to BOEM’s review of the nominations or to any subsequent decision whether to offer all or part of the Call Areas for commercial wind leasing. In providing this information, please refer to the section of this Call entitled, “Requested Information from Interested or Affected Parties.”

**DATES:** BOEM must receive nominations describing your interest in one or more, or any portion of, the Call Areas, by a postmarked date of January 28, 2019 for your nomination to be considered. BOEM requests comments or submissions of information to be postmarked or delivered by this same date.

**ADDRESSES:** If you are submitting a nomination for a lease area in response to this Call, please submit your nomination, following the “Required Nomination Information” section below, to the following address: BOEM, Office of Strategic Resources, 760 Paseo de la Guerra, Santa Barbara, California 93101. In addition to a paper copy of the nomination, include an electronic copy of the nomination on a data storage device. BOEM will list the parties that submitted nominations and the location of the proposed lease areas (i.e., OCS blocks nominated) on the BOEM website after the comment period has closed.

Comments and other information may be submitted by either of the following two methods:

1. **Federal eRulemaking Portal:** http://www.regulations.gov. In the entry entitled, “Enter Keyword or ID,” enter BOEM–2018–0045 and then click “search.” Follow the instructions to submit public comments and view supporting and related materials available for this notice.

2. **U.S. Postal Service or other delivery service.** Send your comments and information to the following address: Bureau of Ocean Energy Management, Office of Strategic Resources, 760 Paseo de la Guerra, Santa Barbara, California 93101.

BOEM will post all responses on http://www.regulations.gov. If you wish to protect the confidentiality of your nominations or comments, clearly mark the relevant sections and request that BOEM treat them as confidential. Please label privileged or confidential information “Contains Confidential Information,” and consider submitting such information as a separate attachment. Treatment of confidential information is addressed in the section of this Call entitled, “Protection of Privileged or Confidential Information.” Information that is not labeled as privileged or confidential will be regarded by BOEM as suitable for public release.

**FOR FURTHER INFORMATION CONTACT:** Jean Thurston, BOEM California Intergovernmental Renewable Energy Task Force Coordinator, BOEM, Office of Strategic Resources, 760 Paseo de la Guerra, Santa Barbara, California 93101, (805) 384–6303 or jean.thurston@boem.gov.

**SUPPLEMENTARY INFORMATION:**

**Authority**

This Call is published pursuant to section 8(p)(3) of the Outer Continental
Call Areas

The three (3) geographically distinct Call Areas described in this notice are located on the OCS offshore California and are the Humboldt Call Area on the north coast and the Morro Bay Call Area and the Diablo Canyon Call Area on the central coast. These areas include 85 whole OCS blocks and 573 partial blocks in total, and comprise approximately 1.073 square statute miles (mi) (687,823 acres). If BOEM determines that there is competitive interest in these areas, BOEM will identify which areas will be subject to an environmental analysis and consideration for leasing as part of the area identification portion of the competitive leasing process. A detailed description of the areas and how they were developed is described in the section of this Call entitled, “Description of the Area.”

Purpose of the Call for Information and Nominations

OCSLA requires BOEM to award leases competitively, unless BOEM determines that there is no competitive interest (43 U.S.C. 1337(p)(3)). On January 14, 2016, BOEM received an unsolicited lease request from Trident Winds, LLC (Trident Winds) for the development of a wind energy project offshore Morro Bay, on the central coast of California. On August 18, 2016, BOEM published the Potential Commercial Leasing for Wind Power on the Outer Continental Shelf—Request for Interest (“RFI”) in the Federal Register to determine if there was competitive interest in the area described by Trident Winds. A copy of BOEM’s RFI is available online at: https://www.boem.gov/81-FR-55228/. In response to the RFI, BOEM received one additional nomination of competitive interest in developing wind energy in the area proposed by Trident Winds.

On September 11, 2018, BOEM received an unsolicited lease request from the Redwood Coast Energy Authority (RCEA) for the development of a wind energy project offshore Humboldt County. RCEA submitted its request after issuing a Request for Qualifications (RFQ) on February 1, 2018, to select one or more qualified entities to enter into a public-private partnership pursuant to their activities to pursue developing an offshore wind energy project off Humboldt County. The RCEA received responses on their RFQ from six entities, and in April 2018 selected partners for the project. The area requested by RCEA in its unsolicited lease request is included in the Humboldt Call Area.

BOEM will use responses to this Call to confirm competitive interest in the portions of the Call Areas for which BOEM already has information, as well as to solicit new expressions of interest in obtaining a lease within the Call Area(s).

BOEM will make a formal determination of competitive interest after reviewing the nominations and comments provided in response to this Call. Depending on the nominations and comments received, BOEM may proceed with the competitive leasing process as set forth in 30 CFR 585.211 through 585.225; may proceed with the noncompetitive leasing process as set forth in 30 CFR 585.231 and 232; or may decide not to proceed with leasing. BOEM may also determine that some of the Call Areas or portions of Call Areas have competitive interest while other area do not. For instance, BOEM may determine that there is no competitive interest in the Humboldt Call Area and that there is competitive interest in the Morro Bay and Diablo Canyon Call Areas. In this case, BOEM could proceed with the noncompetitive leasing process for the Humboldt Call Area and with the competitive leasing process for the Morro Bay and Diablo Canyon Call Areas. We explain these processes in detail in the section of this notice entitled, “BOEM’s Planning and Leasing Process.”

We note that a lease, whether issued through a competitive or noncompetitive process, does not grant the lessee the right to construct any facilities on the lease. The lease only grants the lessee the exclusive right to submit site assessment and construction and operations plans to BOEM, which BOEM must first approve before the lessee may proceed to the next stages of the process (30 CFR 585.600 and 585.601).

Whether competitive or noncompetitive, the leasing process will include subsequent opportunities for public input, and any proposed actions will be reviewed thoroughly for potential environmental impacts and multiple use conflicts. BOEM has not yet determined which area(s) may be offered for lease, if any, has/have not yet been determined, and may include less than the total footprint of any Call Areas or may offer no leasing at all.

1 Background

1.1 Statutory Authorization

Section 8(p) of OCSLA, authorizes the Secretary of the Interior (“Secretary”) to grant leases, easements, or rights-of-way (ROWs) on the OCS for activities not previously authorized by the OCS Lands Act or other applicable law. Under subsection 8(p)(1)(C), the Secretary of the Interior may issue leases for activities that produce or support production, transportation, or transmission of energy from sources other than oil or gas, including renewable energy sources. Section 8(p) also requires the Secretary to issue any necessary regulations to carry out this authority. Regulations were issued for this purpose on April 29, 2009, and are codified in BOEM regulations at 30 CFR part 585. The Secretary has delegated the authority to issue leases, easements, and ROWs to the Director of BOEM.

1.2 Offshore Wind Energy Planning Efforts in California

BOEM appreciates the importance of coordinating its planning endeavors with other OCS users, relevant Federal and state agencies, and tribes. BOEM and the State of California, through the leadership of the California Energy Commission, have engaged in a collaborative, data-based offshore wind energy planning process to foster coordinated and informed decisions about California’s shared ocean resources and the many users who depend on them. This outreach has consisted of numerous public meetings, webinars, and briefings with coastal communities, fishing communities, federally and non-federally recognized tribes, state and Federal agencies, academia and scientists, environmental non-governmental organizations (NGOs), and the offshore renewable energy industry. The summary report on this outreach can be viewed at: https://www.boem.gov/California-Outreach-Summary-Report/. Additional information gathered by BOEM and the State of California during the offshore wind energy planning process, including maps and spatially represented data, is available online at: https://coastalwind.databasin.org/.

1.3 BOEM California Intergovernmental Renewable Energy Task Force

At the request of Governor Brown, BOEM established an Intergovernmental Renewable Energy Task Force (Task Force) with California in 2016 to facilitate coordination among relevant Federal agencies and affected state, local, and tribal governments.
throughout the leasing process. The first Task Force meeting was held on October 13, 2016, and a second Task Force meeting was held on September 17, 2018. Meeting materials are available on the BOEM website at: https://www.boem.gov/California/.

1.4 Actions Taken by the State of California in Support of Renewable Energy Development

The State of California established a Renewable Portfolio Standard (RPS) in 2002. California expanded the RPS in 2015 through passage of Senate Bill 350, the Clean Energy and Pollution Reduction Act, and further expanded the RPS in 2018 through passage of Senate Bill (SB) 100. SB 100 increased the state’s RPS requirements for powering the electricity system from renewable energy resources. The legislation requires 50 percent powering of renewable energy resources. The legislation requires 50 percent powering from renewable resources by 2025, 60 percent by 2030, and 100 percent powering from zero-carbon resources by December 31, 2045, for retail sales of electricity to California end-use customers and electricity procured to serve state agencies. Additional information about California’s RPS is available at: www.cpuc.ca.gov/RPS_Homepage. The full text of SB 100 is available at: https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB100.

2 BOEM’s Environmental Review Process

Before deciding whether and where leases may be issued within the Call Areas, BOEM will prepare an environmental assessment (EA) under the National Environmental Policy Act (NEPA) and conduct consultations to consider the environmental consequences associated with issuing commercial wind leases. As the issuance of a lease does not grant the right to construct any facilities within the lease, the EA will consider reasonably foreseeable environmental consequences associated with leasing, site assessment and site characterization activities (including geophysical, geotechnical, archaeological, and biological surveys). If BOEM issues a lease and the lessee proposes the construction and operation of an offshore wind energy facility, BOEM would consider the environmental effects of such construction and operation under a separate, project-specific NEPA process, which would include additional opportunities for public involvement. BOEM would also conduct consultations under other authorities, including, but not limited to, the Coastal Zone Management Act (CZMA), Endangered Species Act (ESA), the Magnuson-Stevens Fishery Conservation and Management Act, Section 106 of the National Historic Preservation Act (NHPA), and Executive Order 13175 (“Consultation and Coordination with Tribal Governments”).

3 BOEM’s Planning and Leasing Process

3.1 Determination of Competitive Interest

43 U.S.C. 1337(p)(3) states that “the Secretary shall issue a lease, easement, or right-of-way . . . on a competitive basis unless the Secretary determines after public notice of a proposed lease, easement, or right-of-way that there is no competitive interest.” Accordingly, BOEM must first determine whether there is competitive interest in acquiring a lease within the Call Area to develop offshore wind energy. At the conclusion of the comment period for this Call, BOEM will review the nominations received and determine if competitive interest exists in any of the call areas. For areas with two or more valid nominations, BOEM may consider proceeding with competitive leasing as described in the section of this Call entitled “Competitive Leasing Process.” For areas where BOEM determines that there is only one interested entity, BOEM may consider proceeding with noncompetitive leasing, as described in the section entitled “Noncompetitive Leasing Process.”

If BOEM determines that competitive interest exists and BOEM identifies those areas as appropriate to lease, BOEM may hold a competitive lease sale on any or all portions of the Call Area. In the event BOEM holds such a lease sale, all qualified bidders, including those bidders which did not submit a nomination in response to this Call, will be able to participate in the lease sale.

BOEM will not issue any leases until it has completed all required consultations and environmental analysis, which include the opportunity for public comment. Furthermore, BOEM reserves the right not to lease certain nominated areas, or modify such areas from their original, proposed form before offering them for lease.

3.2 Competitive Leasing Process

BOEM will follow the steps required by 30 CFR 585.211 through 585.225 if it decides to proceed with the competitive leasing process for any areas after receiving responses and nominations for this Call.

(1) Area Identification: After determining the existence of competitive interest based on the information it receives in response to this Call, BOEM will identify the area(s) that will be subject to environmental analysis and consideration for leasing. Any area identified will constitute a Wind Energy Area (WEA) and will be subject to environmental analysis as described above, conducted in consultation with appropriate Federal agencies, states, local governments, tribes, and other interested parties.

(2) Proposed Sale Notice (PSN): If BOEM decides to proceed with a competitive lease sale within any WEA after completion of its environmental analysis, BOEM will publish a PSN in the Federal Register with a comment period of 60 days. The PSN will describe any area BOEM intends to offer for leasing, the proposed conditions of a lease sale, the proposed auction format, and the lease instrument, including lease addenda. Additionally, the PSN will describe the criteria and process for evaluating bids in the lease sale.

(3) Final Sale Notice (FSN): After considering the comments on the PSN, if BOEM decides to proceed with a competitive lease sale, it will publish the FSN in the Federal Register at least 30 days before the date of the lease sale.

(4) Bid Submission and Evaluation: Following publication of the FSN in the Federal Register, BOEM would offer the lease areas through a competitive sale process, using procedures specified in the FSN. The conduct of the sale, including bids and bid deposits, would be reviewed for technical and legal adequacy. BOEM will ensure that bidders have complied with all applicable regulations. BOEM reserves the right to reject any or all bids and/or withdraw an offer to lease an area, even after bids have been submitted.

(5) Issuance of a Lease: Following the selection of any winning bid by BOEM, the successful bidder would be notified of the decision and provided a set of official lease documents for execution. Any successful bidder would be required to sign and return the lease, pay the remainder of the bonus bid, if applicable, and file the required financial assurance within 10 business days of receiving the lease documents. Upon receipt of the required payments, financial assurance, and properly signed lease forms, BOEM may execute a lease with the successful bidder.

3.3 Noncompetitive Leasing Process

BOEM’s noncompetitive leasing process would include the following steps:

(1) Determination of No Competitive Interest: If, after evaluating all relevant
information, including responses to this Call, BOEM determines there is no competitive interest in all or a portion of the Call Areas, it may proceed with the noncompetitive lease issuance process pursuant to 30 CFR 585.231 and 232. BOEM would seek to determine if the sole respondent, who nominated a particular area, intends to proceed with acquiring the lease; if so, the respondent would be required to submit an acquisition fee as specified in 30 CFR 585.502(a). After receiving the acquisition fee, BOEM would follow the process outlined in 30 CFR 585.231(3) through (i), which would include the publication of a Determination of No Competitive Interest in the Federal Register.

(2) Review of Lease Request: BOEM would comply with the relevant requirements of NEPA, CZMA, ESA, NHPA and other applicable Federal statutes before issuing a lease noncompetitively. Further, BOEM would coordinate and consult, as appropriate, with relevant Federal agencies, affected or interested parties, and affected state and local governments in formulating lease terms, conditions, and stipulations.

(3) Lease Issuance: After completing its review of the lease request, BOEM may offer a noncompetitive lease. Within 10 business days of receiving the lease, the lessee must execute it and provide a $100,000 lease-specific bond, pursuant to 30 CFR 585.515, to guarantee compliance with all terms and conditions of the lease. Within 45 days of receiving the lease, the lessee must pay BOEM the first 12 months’ rent.

4 Development of the Call Areas

BOEM delineated the Call Areas in consultation with several parties, including the State of California and the Task Force. In coordination with the State of California, BOEM held multiple stakeholder outreach meetings in northern and central California to obtain input into the development of the Call Areas and gather data and information to use in BOEM’s decision making process. More information on these meetings can be found in this notice under “Offshore Wind Energy Planning Efforts in California.” The Call Areas represent portions of the OCS that BOEM has identified to solicit information and nominations so that potential use conflicts can be analyzed and considered in the Area ID stage of the leasing process. During the process of delineating the California Call Areas, BOEM determined that the following areas would not be appropriate for leasing and development at this time:

1. Areas in water depths beyond 1,100 meters. Based on a National Renewable Energy Laboratory (NREL) technical report (NREL, TP-6240-55049, Improved Offshore Wind Resource Assessment in Global Climate Stabilization Scenarios, 2012), BOEM considers 1,100 meters to be a reasonable limit on water depth based on technological feasibility at this time.

2. National Marine Sanctuaries. BOEM lacks the authority to lease within the boundaries of National Marine Sanctuaries, and removed these areas offshore California from consideration, including: Greater Farallones, Cordell Bank, Monterey Bay, and Channel Islands National Marine Sanctuaries.

3. Areas on the OCS that have wind speeds estimated at less than 7 meters per second. These areas were excluded based on a NREL’s 2016 Offshore Wind Energy Resource Assessment for the United States, available at: www.nrel.gov/docs/fy16osti/66599.pdf.

4. Areas with high levels of fishing activity. BOEM recognizes that several commercial and recreational fisheries operate within, or in proximity to, the Call Areas. Fishing industry representatives have provided comments and information to BOEM during meetings and discussions during outreach in 2017 and 2018. Based on these discussions thus far, and data and information gathered during the offshore wind energy planning efforts, areas closer to shore tend to have higher concentrations of commercial and recreational fishing activities and were removed from consideration for leasing.

Fishing information, including maps and spatially represented data, gathered during the offshore wind energy planning process is available online at: https://databasin.org/gallerys/ae21ddebe4fd642f1a382f9dbad8c898d.b. BOEM will continue with outreach to the fishing industry throughout the leasing and planning process. BOEM is requesting additional information regarding recreational and commercial fisheries that operate within the Call Areas and will consider that information at the Area Identification stage of its planning process. If BOEM concludes that fisheries conflicts cannot be properly mitigated in certain portions of the Call Areas, it may exclude those areas from leasing consideration at the Area Identification stage, during the environmental review process under NEPA, and as a result of essential fish habitat consultations under the Magnuson Stevens Fishery Conservation and Management Act. BOEM may also require measures to mitigate or avoid fishery conflicts at the construction and operations phase of the regulatory process.

5. High concentrations of undersea cables. BOEM removed from consideration, at this time, the portion of the OCS offshore Morro Bay that has a large concentration of undersea cables. Information, including a map of these cable locations, is available online at: https://databasin.org/maps/706cd85bb62bd1db2eb7eb7ab60c9b34/active.

Conversely, BOEM gave preference to areas within close proximity to existing transmission infrastructure that could provide for potential integration into California’s existing electrical grid. These are, on the north coast, Humboldt Bay substation, and on the central coast, Morro Bay and Diablo Canyon substations. Transmission infrastructure information is available online at: https://databasin.org/maps/new#/datasets=422db447c151412d918a3085b31429f8.

BOEM also endeavored to exclude from Call Areas those places where preliminary analysis indicated the presence of high concentrations of marine mammal and avian species potentially impacted by offshore wind development. These preliminary analyses were based on data found online at: https://coaofshorewind.databasin.org/gallerys/1e1e3e6be0646467905ec224a747070428#expand%5b136932%5d. BOEM is presently working with partners developing new environmental datasets and modeling tools, and will further analyze and
assess data received in response to the Call during its Area Identification process. BOEM will utilize information received in response to the Call to assist with verification of migratory periods, persistent or seasonally occurring oceanic habitat features associated with marine birds, mammals, sea turtles, and fish, and periods of high species abundance or diversity that may occur within the Call Areas. BOEM will consider the best available information to identify and assess potential areas of conflict with marine protected species within the Call Areas and consult with resource agencies during the Area Identification process, as necessary.

BOEM’s subsequent analysis during Area Identification will evaluate the Call Areas for their appropriateness for offshore wind development, balanced against potential ocean user conflicts. After conducting environmental reviews and associated consultations, analyzing public comments, and continuing to coordinate with other government agencies through the Task Force, BOEM anticipates developing and requiring terms and conditions at the leasing, site assessment, and/or construction and operations phases of its leasing process to avoid or lessen impacts. This Call will allow stakeholders to provide additional input on these areas prior to further modification during the Area Identification process.

### 4.1 Department of Defense

The Department of Defense (DoD) conducts offshore testing, training, and operations within all or portions of the Call Areas. BOEM is working with DoD to determine potential compatible areas or mitigating measures between military activities and offshore wind development areas. While conflicting uses may require some areas of the OCS to be deferred from leasing, development in other areas where military activities occur may eventually be compatible with conditions and stipulations. These stipulations could include, but may not be limited to: Hold and save harmless agreements; mandatory coordination with DoD on specified activities; restrictions on electromagnetic emissions; curtailment of wind farm operations during specific DoD events; and evacuation procedures from the lease area for safety reasons when notified by the DoD. Interested parties should also be aware that the Morro Bay and Diablo Canyon Call Areas on the central coast contain OCS blocks that have been assessed as incompatible with wind energy development by DoD. DoD is currently reviewing additional detailed project information supplied by the offshore wind energy industry to determine if any of the areas previously identified by DoD as incompatible in the Morro Bay Call Area may be identified as compatible after further analyses. The Diablo Canyon area is heavily utilized by multiple DoD components and based upon current and future expected use, previous assessments have found development there to be incompatible with the wide array of critical DoD activities. The Humboldt Call Area on the north coast is currently designated as “Site-Specific Stipulations” by DoD. This designation means DoD may recommend additional mitigation measures, but does not presently deem offshore wind to be incompatible with its missions.

### 5 Description of the Area

The Humboldt, Morro Bay, and Diablo Canyon. These Call Areas include 85 whole OCS blocks and 573 partial blocks in total, and comprise approximately 1,073 square statute miles (mi²) (687,823 acres). A map of the Call Areas, and associated GIS files, which are located in UTM Zone 10N, NAD 83 Datum, can be found at the following URL: https://www.boem.gov/California.

**Call Area Humboldt**

The boundary of Call Area Humboldt begins at 21 mi offshore the city of Eureka in northern California. The area is about 28 mi in length from north to south and about 14 mi in width from east to west. The entire area is approximately 206 square mi (132,369 acres) and is described in the table below:

<table>
<thead>
<tr>
<th>Protration name</th>
<th>Protration No.</th>
<th>Block No.</th>
<th>Sub-block</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crescent City</td>
<td>NK10–07</td>
<td>6975</td>
<td>I, J, K, L, M, N, O, P.</td>
</tr>
<tr>
<td>Crescent City</td>
<td>NK10–07</td>
<td>7023</td>
<td>L, M, N, O, P.</td>
</tr>
<tr>
<td>Crescent City</td>
<td>NK10–07</td>
<td>7024</td>
<td>C, D, E, F, G, H, I, J, K, L, M, N, O, P.</td>
</tr>
<tr>
<td>Crescent City</td>
<td>NK10–07</td>
<td>7025</td>
<td>All.</td>
</tr>
<tr>
<td>Crescent City</td>
<td>NK10–07</td>
<td>7026</td>
<td>A, B, C, E, F, G, I, J, K, M, N, O.</td>
</tr>
<tr>
<td>Crescent City</td>
<td>NK10–07</td>
<td>7072</td>
<td>D, G, H, K, L, O, P.</td>
</tr>
<tr>
<td>Crescent City</td>
<td>NK10–07</td>
<td>7073</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–07</td>
<td>7074</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–07</td>
<td>7075</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–07</td>
<td>7122</td>
<td>C, D, G, H, J, K, L, O, P.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–07</td>
<td>7123</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–07</td>
<td>7124</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–07</td>
<td>7125</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6023</td>
<td>D.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6025</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6026</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6074</td>
<td>B, C, D, G, H, K, L, O, P.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6075</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6076</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6077</td>
<td>A, B, E.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6124</td>
<td>D, H.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6125</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6175</td>
<td>All.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6176</td>
<td>A, B, E, I.</td>
</tr>
<tr>
<td>Eureka</td>
<td>NK10–10</td>
<td>6225</td>
<td>A, B, C, D, E, F, G, I, J, K, M, N.</td>
</tr>
</tbody>
</table>
Canyon begins 22 mi offshore Los Osos, Call Area Diablo Canyon begins 24 mi offshore Cambria, San Luis Obispo ...................................................... NI10–03 6756 M, N, O, P.
Sur Canyon .............................................................. NI10–02 6490 C, D, H.

Call Area Morro Bay
The boundary of Call Area Morro Bay begins 24 mi offshore Cambria, California. The area is about 27 mi in length from north to south and about 27 mi in width from east to west. The entire area is approximately 311 square mi (199,266 acres) and is described in the table below:

<table>
<thead>
<tr>
<th>Protraction name</th>
<th>Protraction No.</th>
<th>Block No.</th>
<th>Sub-block</th>
</tr>
</thead>
<tbody>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6102</td>
<td>L, P.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6103</td>
<td>M.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6152</td>
<td>D, L, P.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6153</td>
<td>A, B, E, F, I, J, K, L, M, N, O.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6202</td>
<td>D, G, H, K, L, N, O, P.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6203</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6204</td>
<td>I, M.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6251</td>
<td>D, H, K, L, O, P.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6252</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6253</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6254</td>
<td>A, B, E, F, G, I, J, K, L, M, N, O, P.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6301</td>
<td>C, D, G, H, K, L, M, O, P.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6302</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6303</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6304</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6305</td>
<td>A, E, I, M.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6351</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6352</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6353</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6354</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6355</td>
<td>A, B, E, F, I, J, M, N.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6401</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6402</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6403</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6404</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6406</td>
<td>M.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6452</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6453</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6454</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6455</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6457</td>
<td>E, F, I, J, M, N, O.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6501</td>
<td>B, C, D, G, H.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6503</td>
<td>A, B, C, D, E, F, G, H, I, J, L.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6504</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6505</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6506</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6507</td>
<td>All.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6508</td>
<td>I, M, N.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6554</td>
<td>D.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6555</td>
<td>A, B, C, D, G, H.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6556</td>
<td>A, B, C, D, E, F, G, H.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6557</td>
<td>A, B, C, D, E, F, G, H.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6558</td>
<td>A, B, C, E, F, G, H.</td>
</tr>
<tr>
<td>Sur Canyon</td>
<td>NI10–02</td>
<td>6300</td>
<td>O, P.</td>
</tr>
<tr>
<td>Sur Canyon</td>
<td>NI10–02</td>
<td>6490</td>
<td>C, D, H.</td>
</tr>
</tbody>
</table>

Call Area Diablo Canyon
The boundary of Call Area Diablo Canyon begins 22 mi offshore Los Osos, California. The area is about 23 mi in length from north to south and about 30 mi in width from east to west. The entire area is approximately 556 square mi (356,188 acres) and is described in the table below:

<table>
<thead>
<tr>
<th>Protraction name</th>
<th>Protraction No.</th>
<th>Block No.</th>
<th>Sub-block</th>
</tr>
</thead>
<tbody>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6756</td>
<td>M, N, O, P.</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>NI10–03</td>
<td>6757</td>
<td>M, N, O, P.</td>
</tr>
<tr>
<td>Protraction name</td>
<td>Protraction No.</td>
<td>Block No.</td>
<td>Sub-block</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------</td>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td>San Luis Obispo</td>
<td>N10–03</td>
<td>6758</td>
<td>M, N, O, P.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6759</td>
<td>M, N, O, P.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6760</td>
<td>M, N, O, P.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6761</td>
<td>M, N, O, P.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6762</td>
<td>M, N, O, P.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6763</td>
<td>M, N, O, P.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6764</td>
<td>M.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6807</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6808</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6809</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6810</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6811</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6812</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6813</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6814</td>
<td>A, E, I, M.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6856</td>
<td>C, D, G, H, K, L, P.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6857</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6858</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6859</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6860</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6861</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6862</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6863</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6864</td>
<td>A, B, E, F, I, J, M, N.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6906</td>
<td>D, H.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6907</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6908</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6909</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6910</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6911</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6912</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6913</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6958</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6959</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6960</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6961</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6962</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6963</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6964</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6965</td>
<td>A, E, F, I, J, K, M, N, O.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7007</td>
<td>C, D, H.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7008</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7009</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7010</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7011</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7012</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7013</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7014</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7015</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7016</td>
<td>I, M.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7059</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7060</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7061</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7062</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7063</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7064</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7065</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7066</td>
<td>A, E, I, M.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7108</td>
<td>C, D, G, H, K, L, N, O, P.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7109</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7110</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7111</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7112</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7113</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7114</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7115</td>
<td>All.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7116</td>
<td>A, E, I, M.</td>
</tr>
<tr>
<td>Santa Maria</td>
<td>N10–06</td>
<td>6008</td>
<td>B, C, D, F, G, H.</td>
</tr>
<tr>
<td>Santa Maria</td>
<td>N10–06</td>
<td>6009</td>
<td>A, B, C, D, E, F, G, H.</td>
</tr>
<tr>
<td>Santa Maria</td>
<td>N10–06</td>
<td>6010</td>
<td>A, B, C, D, E, F, G, H.</td>
</tr>
</tbody>
</table>
6 Requested Information From Interested or Affected Parties

BOEM requests specific and detailed comments from the public and other interested or affected parties regarding the following features, activities, or concerns in or around Call Areas:

1. Geological, geophysical, and biological conditions (including bottom and shallow hazards and live bottom).
2. Known archaeological and/or cultural resource sites on the seabed.
3. Historic properties potentially affected by site characterization (surveys), site assessment (buoy installation), or commercial wind development. This information will inform BOEM’s review of future undertakings under Section 106 of the NHPA and under NEPA.
4. Other uses, including navigation (in particular, commercial and recreational vessel use), recreation, and fisheries (commercial and recreational).
5. Additional information regarding recreational and commercial fisheries, including, but not limited to, the use of the areas, the fishing gear types used, seasonal use, and recommendations for reducing use conflicts.
6. Available and pertinent data and information concerning renewable energy resources and environmental conditions. Where applicable, spatial information should be submitted in a format compatible with ArcGIS 10.5 in a geographic coordinate system (NAD 83).
7. Information relating to visual resources and aesthetics, the potential impacts of wind turbines to those resources, and potential strategies to help mitigate or minimize any visual effects.
8. Other relevant socioeconomic, biological, and environmental information.
9. Any other relevant information BOEM should consider during its planning and decision-making process for the purpose of issuing leases in the Call Area.

7 Required Nomination Information

If you intend to submit one or more nominations for a commercial wind energy lease within any Call Areas identified in this notice, you must provide the following information for each nomination:

1. The BOEM Protraction name, number, and specific whole or partial OCS blocks within the Call Area(s) that you are interested in leasing, inclusive of any potential buffers with adjacent leases. This information should be submitted as a spatial file compatible with ArcGIS 10.5 in a geographic coordinate system (NAD 83) in addition to your hard copy submittal. If your nomination includes one or more partial blocks, please describe those partial blocks in terms of a sixteenth (i.e., sub-block) of an OCS block.
2. A description of your objectives and the facilities that you would use to achieve those objectives.
3. A preliminary schedule of proposed activities, including those leading to commercial operations.
4. Available and pertinent data and information concerning renewable energy resources and environmental conditions in the area(s) that you wish to lease, including energy and resource data and information used to evaluate the area. Where applicable, spatial information should be submitted in a format compatible with ArcGIS 10.5 in a geographic coordinate system (NAD 83).
5. Documentation demonstrating that you are legally qualified to hold a lease in accordance with the requirements of part 30 of the Code of Federal Regulations. Examples of the documentation appropriate for demonstrating your legal qualifications and related guidance can be found in Chapter 2 and Appendix B of the BOEM Renewable Energy Framework Guide Book available at: http://www.boem.gov/REnGuidebook_03/. The documents you provide to demonstrate your qualifications to lease will be placed in a file kept by BOEM that may be made available for public review. If you wish that any part of your legal qualification documentation be kept confidential, clearly identify what should be kept confidential, and submit it under separate cover (see “Protection of Privileged or Confidential Information Section,” below).
6. Documentation demonstrating that you are technically and financially capable of constructing, operating, maintaining, and decommissioning the facilities described in (2) above, in accordance with the requirements of 30 CFR 585.107(a). Guidance regarding the documentation to demonstrate your technical and financial qualifications can be found at: http://www.boem.gov/Renewable-Energy-Program/Regulatory-Information/QualificationGuidelines.pdf.aspx. Any documentation you submit to demonstrate your legal, technical, and financial qualifications must be provided to BOEM in both paper and electronic formats. BOEM considers an Adobe PDF file on a storage media device to be an acceptable format for an electronic copy.

You are not required to submit a nomination in response to this Call in order to participate in a potential future competitive lease sale offshore California. You will not be able to participate in such a competitive lease sale, however, unless you demonstrate prior to the sale that you are legally, technically, and financially qualified to hold a BOEM renewable energy lease. To ensure that BOEM has sufficient time to process your qualifications package, you should submit this package during the PSN 60-day public comment period. More information can be found at: http://www.boem.gov/Renewable-Energy-Program/Regulatory-Information/QualificationGuidelines.pdf.aspx.

8 Protection of Privileged or Confidential Information

8.1 Freedom of Information Act

BOEM will not disclose privileged or confidential information that you submit if it qualifies for when required by the Freedom of Information Act (FOIA) exemption for trade secrets and commercial or financial information provided that you clearly label the submission with “Contains Confidential Information” and request that BOEM treat it as confidential. Please consider submitting such information as a separate attachment.

BOEM will not treat as confidential any aggregate summaries of such information or comments not containing such confidential or privileged information. Additionally, BOEM will not treat as confidential (1) the legal title or the nominating entity (for example,
the name of your company), or (2) the list of whole or partial blocks that you are nominating. Information that is not labeled as privileged or confidential will be regarded by BOEM as suitable for public release.

8.2 Personal Identifying Information

BOEM does not consider anonymous comments; please include your name and address as part of your submittal. You should be aware that your entire comment, including your name, address, and your personal identifying information, may be made publicly available at any time. All submissions from identified individuals, businesses and organizations will be available for public viewing on regulations.gov. In order for BOEM to withhold from disclosure your personal identifying information, you must identify any information contained in the submittal of your comments that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequence of the disclosure of information, such as embarrassment, injury or other harm.

8.3 Section 304 of the National Historic Preservation Act (16 U.S.C. 470w–3(a))

BOEM is required, after consultation with the Secretary, to withhold the location, character, or ownership of historic resources if it determines that disclosure may, among other things, risk harm to the historic resources or impede the use of a traditional religious site by practitioners. Tribal entities should designate information that falls under Section 304 of NHPA as confidential.

Walter D. Cruickshank,
Acting Director, Bureau of Ocean Energy Management.
[FR Doc. 2018–22879 Filed 10–18–18; 8:45 am]
BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR
Bureau of Ocean Energy Management
[Docket No. BOEM–2018–0010]

Notice of Intent To Prepare an Environmental Impact Statement for Deepwater Wind South Fork, LLC’s Proposed Wind Energy Facility Offshore Rhode Island and Massachusetts


ACTION: Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: Consistent with the regulations implementing the National Environmental Policy Act (NEPA), the Bureau of Ocean Energy Management (BOEM) is announcing its intent to prepare an Environmental Impact Statement (EIS) for the review of a Construction and Operations Plan (COP) submitted by Deepwater Wind South Fork, LLC (DWSF) that would allow it to construct and operate up to 15 turbines, an electric service platform offshore Rhode Island and Massachusetts and an export cable to East Hampton, New York. This Notice of Intent (NOI) serves to announce the EIS scoping process for the DWSF COP. Detailed information about the proposed wind energy facility, including the COP, can be found on BOEM’s website at: https://www.boem.gov/South-Fork/.

DATES: Comments should be submitted no later than November 19, 2018.

FOR FURTHER INFORMATION CONTACT: For information on the DWSF COP EIS, the submission of comments, or BOEM’s policies associated with this notice, please contact Michelle Morin, BOEM Office of Renewable Energy Programs, 45600 Woodland Road, Sterling, Virginia 20166, (703) 787–1340 or michelle.morin@boem.gov.

SUPPLEMENTARY INFORMATION:

Proposed Action: The proposed action is the construction and operation of a wind energy facility as described in the COP submitted by DWSF for the DWSF COP. BOEM determine significant resources and activities, and potential mitigation measures to be analyzed in the EIS, as well as provide additional information. BOEM will also use the NEPA commenting process to initiate the Section 106 consultation process under the National Historic Preservation Act (54 U.S.C. 300101 et seq.), as permitted by 36 CFR 800.2(d)(3).

Through this notice, BOEM additionally intends to inform its Section 106 consultation by seeking public comment and input regarding the identification of historic properties or potential effects to historic properties from activities associated with approval of the DWSF COP.

Pursuant to the regulations implementing NEPA (42 U.S.C. 4321 et seq.), BOEM will hold public scoping meetings for the DWSF COP. BOEM’s scoping meetings will be held at the following places and times:

• Amagansett, New York: Monday, November 5, 2018; American Legion Post 419, 15 Montauk Highway (across from Brent’s), Amagansett, New York 11930; Open House 5:00–8:00 p.m.; Presentation and Q&A 6:00 p.m.
• New Bedford, Massachusetts: Wednesday, November 7, 2018; University of Massachusetts Dartmouth School for Marine Science and Technology East, 836 South Rodney French Boulevard, New Bedford, Massachusetts 02744; Open House 5:00–8:00 p.m.; Presentation and Q&A 6:00 p.m.
• Narragansett, Rhode Island: Thursday, November 8, 2018; Narragansett Community Center, 53 Mumford Road, Narragansett, Rhode Island 02882; Open House 5:00–8:00 p.m.; Presentation and Q&A 6:00 p.m.

Cooperating Agencies: BOEM invites other Federal agencies and state, tribal, and local governments to consider becoming cooperating agencies in the preparation of its EIS analyzing the proposed DWSF COP. According to Council on Environmental Quality (CEQ) guidelines, qualified agencies and governments are those with “jurisdiction by law or special expertise.” Potential cooperating agencies should consider their authority and capacity to assume the responsibilities of a cooperating agency, and should be aware that an agency’s role in the environmental analysis neither enlarges nor diminishes the final decision-making authority of any other agency involved in the NEPA process. Upon request, BOEM will provide potential cooperating agencies with a written summary of expectations for cooperating agencies, including time schedules and critical action dates, milestones, responsibilities, scope and
detail of cooperating agencies’ contributions, and availability of pre-decisional information. BOEM anticipates this summary will form the basis for a Memorandum of Agreement between BOEM and any non-Interior Department cooperating agency. Agencies should also consider the “Factors for Determining Cooperating Agency Status” in Attachment 1 to CEQ’s January 30, 2002, Memorandum for the Heads of Federal Agencies: Cooperating Agencies in Implementing the Procedural Requirements of the National Environmental Policy Act. This document is available on the internet at: http://energy.gov/sites/prod/files/nepa_documents/RedDon/G-CEQ-CoopAgenciesImplena.pdf. BOEM, as the lead agency, will not provide financial assistance to cooperating agencies.

Even if a governmental entity is not a cooperating agency, it will have opportunities to provide information and comments to BOEM during the public input stages of the NEPA process. Comments: Federal agencies, tribal, state, and local governments, and other interested parties are requested to comment on the scope of this EIS, significant issues that should be addressed, and alternatives that should be considered. Comments can be submitted in any of the following ways:

1. In written form, delivered by hand or by mail, enclosed in an envelope labeled, “Deepwater Wind South Fork COP EIS” and addressed to Program Manager, Office of Renewable Energy, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, Virginia 20166. Comments must be received or postmarked no later than November 19, 2018; or
2. Through the regulations.gov web portal: Navigate to http://www.regulations.gov and search for Docket No. BOEM–2018–0010. Click on the “Comment Now!” button to the right of the document link. Enter your information and comment, then click “Submit.”

BOEM does not consider anonymous comments. Please include your name and address as part of your submittal. BOEM makes all comments, including the names and addresses of respondents, available for public review online and during regular business hours. Individual respondents may request that BOEM withhold their names or addresses from the public record; however, BOEM cannot guarantee that it will be able to do so. If you wish your name or address to be withheld, you must state your preference prominently at the beginning of your comment. All submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses will be made available for public inspection in their entirety.

Authority: This NOI is published pursuant to the regulations (40 CFR 1501.7) implementing the provisions of NEPA.

Dated: October 12, 2018.

William Yancey Brown,
Chief Environmental Officer, Bureau of Ocean Energy Management.

[FR Doc. 2018–22880 Filed 10–18–18; 8:45 am]
BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1138]

Certain LTE- and 3G-Compliant Cellular Communications Devices Institution of Investigation


ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on September 14, 2018, under section 337 of the Tariff Act of 1930, as amended, on behalf of INVIT SPE LLC of San Francisco, California. 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 LTE- and 3G-compliant cellular communications devices by reason of infringement of certain claims of U.S. Patent No. 6,760,590 (“the ’590 patent”); U.S. Patent No. 7,206,587 (“the ’587 patent”); U.S. Patent No. 7,764,711 (“the ’711 patent”); U.S. Patent No. 7,848,439 (“the ’439 patent”); and U.S. Patent No. 7,339,949 (“the ’949 patent”). The complaint further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complaint requests that the Commission institute an investigation and, after the investigation, issue 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 https://www.usitc.gov. The public record for this investigation may be viewed on the Commission’s electronic docket (EDIS) at https://edis.usitc.gov.


SUPPLEMENTARY INFORMATION:


Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on October 15, 2018, 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 products identified in paragraph (2) by reason of infringement of one or more of claims 3 and 4 of the ’590 patent; claim 4 of the ’587 patent; claims 1, 2, and 4 of the ’711 patent; claims 1–3 of the ’439 patent; and claim 16 of the ’949 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission’s Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is “personal electronic devices that are compliant with the LTE and/or 3G 3GPP specifications, and which enable LTE and/or 3G data transfer and communications”;

(3) Pursuant to Commission Rule 210.50(b)(1), 19 CFR 210.50(b)(1), the presiding administrative law judge shall take evidence or other information and hear arguments from the parties and other interested persons with respect to
the public interest in this investigation, as appropriate, and provide the
Commission with findings of fact and a recommended determination on this
issue, which shall be limited to the statutory public interest factors set forth
in 19 U.S.C. 1337(d)(1), (f)(1), (g)(1);
(4) 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:
INVT SPE LLC, One Market Plaza, Spear
Tower, 42nd Floor, San Francisco, CA
94105.
(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:
Apple Inc., 1 Infinite Loop, Cupertino,
CA 95014.
HTC Corporation, 23 Xinghua Road,
Taoyuan City, Taoyuan County 330,
Taiwan.
HTC America, Inc., 308 Occidental Ave.
S, Suite 300, Seattle, WA 98104.
ZTE Corporation, ZTE Plaza, Keji Road
South, Hi-Tech Industrial Park,
Nanshan District, Guangdong
Province, 518057, China.
ZTE (USA) Inc., 2425 N Central
Expressway, Suite 800, Richardson,
TX 75080.
(c) The Office of Unfair Import
Investigations, U.S. International Trade
Commission, 500 E Street SW, Suite
401, Washington, DC 20436; and
(5) 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
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.
Lisa Barton,
Secretary to the Commission.

DEPARTMENT OF JUSTICE
Antitrust Division

Notice Pursuant to the National
Cooperative Research and Production
Act of 1993—Consortium for Execution
of Rendezvous and Servicing
Operations

Notice is hereby given that, on
September 10, 2018, pursuant to Section
6(a) of the National Cooperative
Research and Production Act of 1993,
15 U.S.C. 4301 et seq. ("the Act"),
Consortium for Execution of
Rendezvous and Servicing Operations
("CONFERS") has filed written
notifications simultaneously with the
Attorney General and the Federal Trade
Commission disclosing (1) the identities
of the parties to the venture and (2) the
nature and objectives of the venture.
The notifications were filed for the
purpose of invoking the Act’s provisions
limiting the recovery of antitrust
plaintiffs to actual damages under
specified circumstances.
Pursuant to Section 6(b) of the Act,
the identities of the parties to the
venture are: Altius Space Machines,
Inc., Broomfield, CO; Analytical
Graphics, Inc., Exton, PA; Astroscale
PTE, LTD., Tokyo, JAPAN; Ball
Aerospace and Technology Corp.,
Boulder, CO; Chandah Space
Technologies, Houston, TX; Hoffer Flow
Controls, Inc. Elizabeth City, NC; iBOSS
gmbH, Aachen, GERMANY; MacDonald,

DEPARTMENT OF JUSTICE
Drug Enforcement Administration

Bulk Manufacturer of Controlled
Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrant listed below
has applied for and been granted
registration by the Drug Enforcement
Administration (DEA) as a bulk
manufacturer of various classes of
schedule I and II controlled substances.

SUPPLEMENTARY INFORMATION: The
company listed below applied to be
registered as a bulk manufacturer of
various basic classes of controlled
substances. Information on a previously
published notice is listed in the table
below. No comments or objections were
submitted for this notice.

<table>
<thead>
<tr>
<th>Company</th>
<th>FR Docket</th>
<th>Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>Siegfried USA, LLC</td>
<td>83 FR 32905</td>
<td>July 16, 2018</td>
</tr>
</tbody>
</table>
The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of this registrant to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company’s maintenance of effective controls against diversion by inspecting and testing the company’s physical security systems, verifying the company’s compliance with state and local laws, and reviewing the company’s background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed company.

Dated: October 10, 2018.

John J. Martin,
Assistant Administrator.

[FR Doc. 2018–22829 Filed 10–18–18; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
[Docket No. DEA–392]
Importer of Controlled Substances Registration

ACTION: Notice of registration.

The DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and 958(a) and determined that the registration of the listed registrants to import the applicable basic classes of schedule I or II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each company’s maintenance of effective controls against diversion by inspecting and testing each company’s physical security systems, verifying each company’s compliance with state and local laws, and reviewing each company’s background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer of schedule I or II controlled substances to the above listed companies.

Dated: October 10, 2018.

John J. Martin,
Assistant Administrator.

[FR Doc. 2018–22830 Filed 10–18–18; 8:45 am]
BILLING CODE 4410–09–P

<table>
<thead>
<tr>
<th>Company</th>
<th>FR Docket</th>
<th>Published</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chattem Chemicals, Inc</td>
<td>83 FR 39129</td>
<td>August 8, 2018.</td>
</tr>
<tr>
<td>Myoderm</td>
<td>83 FR 39130</td>
<td>August 8, 2018.</td>
</tr>
<tr>
<td>Anderson Brecon, Inc</td>
<td>83 FR 39128</td>
<td>August 8, 2018.</td>
</tr>
</tbody>
</table>

**SUMMARY:** Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as importers of various classes of schedule I or II controlled substances.

**SUPPLEMENTARY INFORMATION:** The companies listed below applied to be registered as importers of various basic classes of controlled substances. Information on previously published notices are listed in the table below. No comments or objections were submitted and no requests for hearings were submitted for these notices.

**DEPARTMENT OF JUSTICE**
**Drug Enforcement Administration**

[Docket No. DEA–392]

**Importer of Controlled Substances Application: Noramco Inc.**

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 19, 2018. Such persons may also file a written request for a hearing on the application on or before November 19, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearings must be sent to: Drug Enforcement Administration, Attention: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearings should also be sent to: (1) Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**Controlled substance**

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Drug code</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marihuana Extract</td>
<td>7350</td>
<td>I</td>
</tr>
</tbody>
</table>
The company plans to import phenylaceton (8501), and poppy straw concentrate (9670) to bulk manufacture other controlled substances for distribution to its customers. The company plans to import an intermediate form of tapentadol (9780) to bulk manufacture tapentadol (9780) for distribution to its customers.

The company plans to import impurities of buprenorphine that have been determined by DEA to be captured under drug code (9333) thebaine. In reference to drug codes 7360 and 7370, the company plans to import a synthetic cannabidiol and a synthetic tetrahydrocannabinol. No other activity for these drug codes is authorized for this registration. Placement of these drug codes onto the company’s registration does not translate into automatic approval of subsequent permit applications to import controlled substances. Approval of permit applications will occur only when the registrant’s business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: October 10, 2018.

John J. Martin,
Assistant Administrator.

BILLING CODE 4410–09–P

### DEPARTMENT OF JUSTICE

#### Drug Enforcement Administration

[**Docket No. DEA–392**]

**Importer of Controlled Substances Application: Fisher Clinical Services, Inc.**

**ACTION:** Notice of application.

**DATES:** Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before November 19, 2018. Such persons may also file a written request for a hearing on the application on or before November 19, 2018.

**ADDRESSES:** Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

**SUPPLEMENTARY INFORMATION:** The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this notice that on June 4, 2018, Fisher Clinical Services, Inc., 754 Schantz Road, Allentown, Pennsylvania 18106 applied to be registered as an importer of the following basic class of controlled substance:

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Drug code</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psilocybin</td>
<td>7437</td>
<td>I</td>
</tr>
</tbody>
</table>

The company plans to import the listed controlled substance for clinical trials.

Dated: October 10, 2018.

John J. Martin,
Assistant Administrator.

BILLING CODE 4410–09–P

### DEPARTMENT OF JUSTICE

#### [OMB Number 1121–0184]

**Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Comments Requested: 2019 School Crime Supplement (SCS) to the National Crime Victimization Survey (NCVS)**

**AGENCY:** Bureau of Justice Statistics, Department of Justice.

**ACTION:** 30-Day notice.

**SUMMARY:** The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, 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.

**DATES:** Comments are encouraged and will be accepted for 30 days until November 19, 2018.

**FOR FURTHER INFORMATION CONTACT:** If you 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 Rachel Morgan, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: rachel.morgan@usdoj.gov; telephone: 202–616–1707).

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 Bureau of Justice Statistics, 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;
— Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
— 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: Revision of a currently approved collection.

(2) The Title of the Form/Collection: 2019 School Crime Supplement to the National Crime Victimization Survey (NCVS).

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection: The form number for the questionnaire is SCS–1. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: The survey will be administered to persons ages 12 to 18 in NCVS sampled households in the United States from January through June 2019. The SCS collects, analyzes, publishes, and disseminates statistics on the students’ victimization, perceptions of school environment, and safety at school.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: An estimate of the total number of respondents is 8,567 persons ages 12 to 18. Of the 8,567 SCS respondents, 86% or 7,402 are expected to complete the long SCS interview (entire SCS questionnaire) which will take an estimated 16 minutes (0.27 hours) to complete. The remaining 14% or 1,165 SCS respondents are expected to complete the short interview (i.e., will be screened out for not being in school), which will take an estimated 2.5 minutes (0.04 hours) to complete. Respondents will be asked to respond to this survey only once during the six-month period. The burden estimates are based on data from the prior administration of the SCS.

(6) An estimate of the total public burden (in hours) associated with the collection: There are an estimated 2,046 annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, 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: October 16, 2018

Melody Braswell,
Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2018–22804 Filed 10–18–18; 8:45 am]
BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE
Office of Justice Programs
[OMB Number 1121–0255]

Agency Information Collection Activities: Proposed eCollection eComments Requested; Reinstatement, With Change, of a Previously Approved Collection: 2018 Census of Law Enforcement Training Academies (CLETA)

AGENCY: Bureau of Justice Statistics, Office of Justice Programs, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, 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. The proposed information collection was previously published in the Federal Register on Monday, July 23, 2018, allowing a 60-day comment period. Following publication of the 60-day notice, the Bureau of Justice Statistics received one communication containing general comments on the importance of the collection.

DATES: Comments are encouraged and will be accepted for 30 days until November 19, 2018.

FOR FURTHER INFORMATION CONTACT: If you 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 Anthony S. Whyde, Statistician, Law Enforcement Statistics Unit, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: Anthony.Whyde@usdoj.gov; phone: 202–307–0711).

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 Bureau of Justice Statistics, 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;
— Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
— 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: Revision of a currently approved collection.

(2) The Title of the Form/Collection: 2019 School Crime Supplement to the National Crime Victimization Survey (NCVS).

(3) The agency form number, if any, and the applicable component of the Department sponsoring the collection: OECD number 1121–0255.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: The survey will be administered to persons ages 12 to 18 in NCVS sampled households in the United States from January through June 2019. The SCS collects, analyzes, publishes, and disseminates statistics on the students’ victimization, perceptions of school environment, and safety at school.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: An estimate of the total number of respondents is 8,567 persons ages 12 to 18. Of the 8,567 SCS respondents, 86% or 7,402 are expected to complete the long SCS interview (entire SCS questionnaire) which will take an estimated 16 minutes (0.27 hours) to complete. The remaining 14% or 1,165 SCS respondents are expected to complete the short interview (i.e., will be screened out for not being in school), which will take an estimated 2.5 minutes (0.04 hours) to complete. Respondents will be asked to respond to this survey only once during the six-month period. The burden estimates are based on data from the prior administration of the SCS.

(6) An estimate of the total public burden (in hours) associated with the collection: There are an estimated 2,046 annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, 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: October 16, 2018

Melody Braswell,
Department Clearance Officer for PRA, U.S. Department of Justice.
DEPARTMENT OF JUSTICE
Office of Justice Programs

[OMB Number 1121—NEW]

Agency Information Collection Activities; Proposed eCollection; eComments Requested; New Collection: Survey of State Attorneys General Offices (SSAGO): Human Trafficking

AGENCY: Bureau of Justice Statistics, Office of Justice Programs, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, 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 on August 6, 2018, allowing for a 60 day comment period. Six comments from the public were received during this period and are thoroughly addressed in the supporting statement for this collection. Briefly, three comments stated support for the survey and three comments requested more information but did not provide any follow-up comments.

DATES: Comments are encouraged and will be accepted for an additional 30 day period ending on November 19, 2018.

FOR FURTHER INFORMATION CONTACT: If you 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 Suzanne M. Strong, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: Suzanne.M.Strong@usdoj.gov; telephone: 202–616–3666). Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 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 agencies 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
—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 collection.
(2) Title of the Form/Collection: Survey of State Attorneys General Offices (SSAGO)—Human Trafficking.
(3) Agency form number, if any, and the applicable component of the Department sponsoring the collection: The form number for the questionnaire is SSAGO–2. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

Affected public who will be asked or required to respond, as well as a brief abstract: Respondents will be state attorneys general or deputy attorneys within the state and territory attorneys general offices who work on human trafficking matters. The SSAGO:HT will be conducted for a three (3) month period. The survey collects data on the staffing of state attorneys general offices, including the total number of deputy attorneys general and access to support staff. The survey also collects information on the types and numbers of human trafficking matters referred to the state attorneys general offices, the sources of the referrals of human trafficking matters, the estimates of labor and sex trafficking cases, the types of victims in labor and sex trafficking cases, the types of offenders of labor and sex trafficking cases, the manner in which criminal and civil human trafficking cases were closed in court, and state attorneys general offices’ participation in state and federal human trafficking task forces. BJS plans to publish this information in reports and reference it when responding to queries from the U.S. Congress, Executive Office...
of the President, the U.S. Supreme Court, state officials, international organizations, researchers, students, the media, and others interested in criminal justice statistics.

(4) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply: An agency-level survey will be sent to the 56 state and territory attorneys general offices. The expected burden placed on these respondents is 25 minutes to complete the survey, with an additional 5 minutes to locate any additional persons necessary to complete the survey.

(6) An estimate of the total public burden (in hours) associated with the collection: There are an estimated 28 total burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.


Melody Braswell,
Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2018–22802 Filed 10–18–18; 8:45 am]
BILLING CODE 4410–18–P

DEPARTMENT OF LABOR
Office of Federal Contract Compliance Programs

Leadership in Equal Access and Diversity Award; New Information Collection Requirements; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995. The program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Federal Contract Compliance Programs (OFCCP) is soliciting comments concerning its proposal to obtain approval from the Office of Management and Budget (OMB) to implement the Leadership in Equal Access and Diversity (LEAD) award. OFCCP will be sharing the information with DOL’s Women’s Bureau for the purpose of partnering with them in support of the award. A copy of the proposed information collection request can be obtained by contacting the office listed below in the FOR FURTHER INFORMATION CONTACT section of this Notice or by accessing it at www.regulations.gov.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before December 18, 2018.

ADDRESSES: You may submit comments by any of the following methods:

Electronic comments: Addressed to Harvey D. Fort, Acting Director, Division of Policy and Program Development, Office of Federal Contract Compliance Programs, 200 Constitution Avenue NW, Room C–3325, Washington, DC 20210.

Instructions: Please submit one copy of your comments by only one method. For faster submission, we encourage commenters to transmit their comment electronically via the www.regulations.gov website. Comments that are mailed to the address provided above must be postmarked before the close of the comment period. All submissions must include OFCCP’s name for identification. Comments submitted in response to the notice, including any personal information provided, become a matter of public record and will be posted on www.regulations.gov. Comments will also be summarized and/or included in the request for OMB approval of the information collection request.

FOR FURTHER INFORMATION CONTACT: Harvey D. Fort, Acting Director, Division of Policy and Program Development, Office of Federal Contract Compliance Programs, Room C–3325, 200 Constitution Avenue NW, Washington, DC 20210, Telephone: (202) 693–0103 (voice) or (202) 693–1337 (TTY) (these are not toll-free numbers). Copies of this notice may be obtained in alternative formats (large print, braille, audio recording) upon request by calling the numbers listed above.

SUPPLEMENTARY INFORMATION:

I. Background

OFCCP administers and enforces the three nondiscrimination and equal employment opportunity laws listed below:

• Executive Order 11246, as amended (E.O. 11246)
• Section 503 of the Rehabilitation Act of 1973, as amended (Section 503)
• Vietnam Era Veterans’ Readjustment Assistance Act of 1974, as amended (VEVRAA)

These authorities prohibit employment discrimination by covered federal contractors and subcontractors and require that they provide equal employment opportunities regardless of race, color, religion, sex, sexual orientation, gender identity, national origin, disability, or status as a protected veteran. Additionally, federal contractors and subcontractors are prohibited from discriminating against applicants and employees for asking about, discussing, or sharing information about their pay or the pay of their co-workers. E.O. 11246 applies to federal contractors and subcontractors and to federally assisted construction contractors holding a Government contract in excess of $10,000, or Government contracts that have, or can reasonably be expected to have, an aggregate total value exceeding $10,000 in a 12-month period. E.O. 11246 also applies to government bills of lading, depositories of federal funds in any amount, and to financial institutions that are issuing and paying agents for U.S. Savings Bonds. Section 503 prohibits employment discrimination against applicants and employees because of physical or mental disability and requires affirmative action to ensure that persons are treated without regard to disability. Section 503 applies to federal contractors and subcontractors with contracts in excess of $15,000. VEVRAA prohibits employment discrimination against protected veterans and requires affirmative action to ensure that persons are treated without regard to their status as a protected veteran. VEVRAA applies to federal contractors and subcontractors with contracts of $150,000 or more. This collection will implement the LEAD award that will recognize federal contractor and subcontractor establishments that have developed and successfully implemented comprehensive equal employment opportunity and nondiscrimination programs.
II. Review Focus

OFCCP is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the compliance assistance functions of the agency that support the agency’s compliance mission, 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
- 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 submissions of responses.

III. Current Actions

OFCCP seeks approval of this new information collection in order to carry out and enhance its responsibilities to enforce the nondiscrimination and affirmative action provisions of the three legal authorities it administers.

Type of Review: New Request.
Title: Contractor Recognition Program—Leadership in Equal Access and Diversity (LEAD) Award.
OMB Number: 1250–[NEW].
Agency Number: None.
Affected Public: Business or other for-profit entities.

Total Respondents for Nominations: 100.
Total Annual Responses for Nominations: 100 biennially.
Average Time per Response for Nominations: 26 hours.
Estimated Total Burden Hours for Nominations: 2,600.
Frequency: Biennially.
Total Burden Cost for Nominations: $88,842.
Total Respondents for Finalists: 6.
Total Annual Responses for Finalists: 6 biennially.
Average Time per Response for Finalists: 28 hours.
Estimated Total Burden Hours for Finalists: 168 hours.
Total Burden Cost for Finalists: $5,741.
Estimated Total Burden Hours (Nominations and Finalists): 2,768 hours.

Total Burden Cost (Nominations and Finalists): $94,583.

Harvey D. Fort,
Acting Director, Division of Policy and Program Development, Office of Federal Contract Compliance Programs.

DEPARTMENT OF LABOR
Mine Safety and Health Administration

Petitions for Modification of Application of Existing Mandatory Safety Standard

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: This notice is a summary of a petition for modification submitted to the Mine Safety and Health Administration (MSHA) by the party listed below.

DATES: All comments on the petition must be received by MSHA’s Office of Standards, Regulations, and Variances on or before November 19, 2018.

ADDRESSES: You may submit your comments, identified by “docket number” on the subject line of the message.

1. Email: zzMSHA-comments@dol.gov. Include the docket number of the petition in the subject line of the message.

The petitioner states that:

1. An alternative method of achieving the mining of such mine by such standard;
2. That the application of such standard will result in a diminution of safety to the miners in such mine.

In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

II. Petition for Modification

Docket Number: M–2018–008–M.

Mines: Columbia Plant, MSHA I.D. No. 38–00138, located in Lexington County, South Carolina.

Regulation Affected: 30 CFR 56.13020
(Use of compressed air).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternative method that will provide no less a degree of safety than that provided by the standard.

The petitioner states that:

1. The alternative method provides a direct reduction of miners’ exposure to respirable dust, thus reducing their health risks. The proposed alternative method has been jointly developed between Unimin Corporation and the National Institute of Occupational Safety and Health (NIOSH) and successfully tested by the NIOSH.

2. The petition proposes the following:

Only miners trained in the operation of the clothes cleaning booth will be permitted to use the booth to clean their clothes.

Petitioner will incorporate the NIOSH Clothes Cleaning Process and manufacturer’s instruction manual into their MSHA Part 48 training plan and train affected miners in the process.

Miners entering the booth will examine valves and nozzles for damage or malfunction and will close the door fully before opening the air

The assistant received and started reading the document.
valve. Any defects will be repaired prior to the booth being used.
—Miners entering the booth will wear eye protection, ear plugs or muffs for hearing protection, and respiratory protection. Respiratory protection will consist of a full-face or half-mask respirator that meets or exceeds the minimum requirements of a N95 filter to which the miner has been fit-tested. As an alternative, the use of a full-face respirator will meet the requirements for eye protection. A sign will be conspicuously posted requiring the use of the above personal protective equipment when the booth is entered.
—Airflow through the booth will be at a sufficient volume to permit no less than the same measure of protection afforded by the standard.
Roslyn B. Fontaine,
Deputy Director, Office of Standards, Regulations, and Variances.
[FR Doc. 2018–22744 Filed 10–18–18; 8:45 am]
BILLING CODE 4520–43–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
[Notice (18–079)]
NASA Advisory Council; Aeronautics Committee; Meeting
AGENCY: National Aeronautics and Space Administration.
ACTION: Notice of meeting.
SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Aeronautics Committee of the NASA Advisory Council (NAC). This meeting will be held for soliciting, from the aeronautics community and other persons, research and technical information relevant to program planning.
DATES: Thursday, November 15, 2018, 10:30 a.m.–5:30 p.m., Local Time.
ADDRESSES: NASA Langley Research Center, 2 Langley Boulevard, Building 2101, Room 305, Hampton, VA 23681.
FOR FURTHER INFORMATION CONTACT: Ms. Irma Rodriguez, Designated Federal Officer, Aeronautics Research Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0984, or irma.r.rodriguez@nasa.gov.
SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting is also available telephonically and by WebEx. You must use a touch-tone telephone to participate in this meeting. Any interested person may dial the USA toll-free conference number 1–888–769–8716, participant passcode: 6813159, followed by the # sign to participate in this meeting by telephone. The WebEx link is https://nasa.webex.com/, the meeting number is 994 496 825, and the password is Je2WcGD*. The agenda for the meeting includes the following topics:
—Subsonic Technology Development Strategy
—Vertical Lift Noise
—Autonomy Update
For NASA Langley Research Center visitor access, please go through the Main Gate and show a valid government-issued identification (i.e., driver’s license, passport, etc.) to the security guard. Inform the security guard that you are attending a meeting in Building 2101. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 15 days prior to the meeting: Full name; gender; date/place of birth; citizenship; passport information (number, country, telephone); visa information (number, type, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee. To expedite admittance, U.S. citizens and Permanent Residents (green card holders) are requested to provide full name and citizenship status no less than 5 working days in advance. Information should be sent to Ms. Irma Rodriguez by fax at (202) 358–4060. For questions, please call Ms. Irma Rodriguez at (202) 358–0984. Attendees will also be required to sign a register prior to entering the meeting room. It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.
Patricia Rausch,
Advisory Committee Management Officer, National Aeronautics and Space Administration.
[FR Doc. 2018–22799 Filed 10–18–18; 8:45 am]
BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
[Notice (18–080)]
Human Exploration and Operations Research Advisory Committee; Meeting
AGENCY: National Aeronautics and Space Administration.
ACTION: Notice of meeting.
SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Human Exploration and Operations Research Advisory Committee.
DATED: November 16, 2018, 9:00 a.m. to 5:00 p.m., Local Time.
SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting is also available telephonically and by WebEx. Any interested person may dial the USA toll free conference call number 1–844–467–6272 or toll number 1–720–259–6462, participant passcode: 535959, followed by the # sign, to participate in this meeting by telephone. The WebEx link is https://nasa.webex.com, the meeting number is 996 592 635, and the password is Exploration@2018.

The agenda for the meeting includes the following topics:

—NASA Space Life and Physical Sciences Research and Applications Status
—Center for the Advancement of Science in Space (CASIS) Status
—Commercial Space Research Opportunities
—Gateway Research Opportunities
—International Space Station (ISS) and Low Earth Orbit (LEO) Commercialization

Attendees will be requested to sign a register and to comply with NASA security requirements, including the presentation of a valid picture ID to Security before access to NASA Headquarters. Foreign nationals attending this meeting will be required to provide a copy of their passport and visa in addition to providing the following information no less than 10 working days prior to the meeting: Full name; gender; date/place of birth; citizenship; visa information (number, type, expiration date); passport information (number, country, expiration date); employer/affiliation information (name of institution, address, country, telephone); title/position of attendee; and home address to Dr. Bradley Carpenter via email at bcarpenter@nasa.gov or by fax at (202) 358–2886. U.S. citizens and Permanent Residents (green card holders) are requested to submit their name and affiliation no less than 3 working days prior to the meeting to Dr. Carpenter. It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Patricia Rausch,
Advisory Committee Management Officer, National Aeronautics and Space Administration.

FOR FURTHER INFORMATION CONTACT: Dr. Bradley Carpenter, Designated Federal Officer, Human Exploration and Operations Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0826, or bcarpenter@nasa.gov.

NATIONAL SCIENCE FOUNDATION
Advisory Committee for Mathematical and Physical Sciences; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Advisory Committee for Mathematical and Physical Science (#66).

Date and Time: November 15, 2018; 12 p.m. to 4:30 p.m. November 16, 2018; 8:30 a.m. to 4:30 p.m.

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314.

Type of Meeting: Open.

Contact Person: Nadège Aoki, National Science Foundation, 2415 Eisenhower Avenue, Room C 9015B, Alexandria, Virginia 22314; Telephone: 703/292–4934.

Purpose of Meeting: To provide advice, recommendations and counsel on major goals and policies pertaining to MPS programs and activities.

Agenda

Thursday, November 15, 2018 12 p.m.–4:30 p.m.

• Update on MPS Activities from Assistant Director Anne Kinney
• Presentation and Discussion—Big Ideas: NSF INCLUDES
• MPS Distinguished Lecture: Does Data Size Matter?
• Presentation and Discussion—Big Ideas: Mid-Scale Research Infrastructure

Friday, November 16, 2018 8:30 a.m.–4:30 p.m.

• Presentations: Upcoming Division Opportunities for Community Input
• Discussion: MPS Strategic Vision for the Future
• Discussion with NSF Director and COO


Crystal Robinson,
Committee Management Officer.

FOR FURTHER INFORMATION CONTACT: Jennifer Munz at the above address or (703) 292–2478.

SUPPLEMENTARY INFORMATION: The membership of the National Science Foundation’s Senior Executive Service Performance Review Board is as follows: F. Fleming Crim, Chief Operating Officer, Chairperson Dianne Campbell Krieger, Chief Human Capital Officer & Division Director, Division of Human Resource Management Dorothy Aronson, Chief Information Officer Anne Kinney, Assistant Director, Directorate for Mathematical & Physical Sciences Suzanne C. Iacono, Office Head, Office of Integrative Activities Michael Wektlow, Deputy Chief Financial Officer and Division Director, Budget Division Joanne Tornow, Acting Assistant Director, Directorate for Biological Sciences Erwin Gianchandani, Assistant Director, Directorate for Computer and Information Science and Engineering

This announcement of the membership of the National Science Foundation’s Senior Executive Service Performance Review Board is made in compliance with 5 U.S.C. 4314(c)(4).

Dated: September 27, 2018.

Jennifer Munz,
Branch Chief, Executive Services, Division of Human Resource Management.

FOR FURTHER INFORMATION CONTACT: Crystal Robinson, Committee Management Officer.

Summary:
The National Science Foundation is announcing the members of the Senior Executive Service Performance Review Board.

For Further Information Contact:
Jennifer Munz at the above address or (703) 292–2478.

SUPPLEMENTARY INFORMATION:
The membership of the National Science Foundation’s Senior Executive Service Performance Review Board is as follows: F. Fleming Crim, Chief Operating Officer, Chairperson Dianne Campbell Krieger, Chief Human Capital Officer & Division Director, Division of Human Resource Management Dorothy Aronson, Chief Information Officer Anne Kinney, Assistant Director, Directorate for Mathematical & Physical Sciences Suzanne C. Iacono, Office Head, Office of Integrative Activities Michael Wektlow, Deputy Chief Financial Officer and Division Director, Budget Division Joanne Tornow, Acting Assistant Director, Directorate for Biological Sciences Erwin Gianchandani, Assistant Director, Directorate for Computer and Information Science and Engineering

This announcement of the membership of the National Science Foundation’s Senior Executive Service Performance Review Board is made in compliance with 5 U.S.C. 4314(c)(4).

Dated: September 27, 2018.

Jennifer Munz,
Branch Chief, Executive Services, Division of Human Resource Management.

FOR FURTHER INFORMATION CONTACT: Crystal Robinson, Committee Management Officer.

Summary:
The National Science Foundation is announcing the members of the Senior Executive Service Performance Review Board.

For Further Information Contact:
Jennifer Munz at the above address or (703) 292–2478.

SUPPLEMENTARY INFORMATION:
The membership of the National Science Foundation’s Senior Executive Service Performance Review Board is as follows: F. Fleming Crim, Chief Operating Officer, Chairperson Dianne Campbell Krieger, Chief Human Capital Officer & Division Director, Division of Human Resource Management Dorothy Aronson, Chief Information Officer Anne Kinney, Assistant Director, Directorate for Mathematical & Physical Sciences Suzanne C. Iacono, Office Head, Office of Integrative Activities Michael Wektlow, Deputy Chief Financial Officer and Division Director, Budget Division Joanne Tornow, Acting Assistant Director, Directorate for Biological Sciences Erwin Gianchandani, Assistant Director, Directorate for Computer and Information Science and Engineering

This announcement of the membership of the National Science Foundation’s Senior Executive Service Performance Review Board is made in compliance with 5 U.S.C. 4314(c)(4).

Dated: September 27, 2018.

Jennifer Munz,
Branch Chief, Executive Services, Division of Human Resource Management.

Summary:
The National Science Foundation is announcing the members of the Senior Executive Service Performance Review Board.

For Further Information Contact:
Jennifer Munz at the above address or (703) 292–2478.

SUPPLEMENTARY INFORMATION:
The membership of the National Science Foundation’s Senior Executive Service Performance Review Board is as follows: F. Fleming Crim, Chief Operating Officer, Chairperson Dianne Campbell Krieger, Chief Human Capital Officer & Division Director, Division of Human Resource Management Dorothy Aronson, Chief Information Officer Anne Kinney, Assistant Director, Directorate for Mathematical & Physical Sciences Suzanne C. Iacono, Office Head, Office of Integrative Activities Michael Wektlow, Deputy Chief Financial Officer and Division Director, Budget Division Joanne Tornow, Acting Assistant Director, Directorate for Biological Sciences Erwin Gianchandani, Assistant Director, Directorate for Computer and Information Science and Engineering

This announcement of the membership of the National Science Foundation’s Senior Executive Service Performance Review Board is made in compliance with 5 U.S.C. 4314(c)(4).

Dated: September 27, 2018.

Jennifer Munz,
Branch Chief, Executive Services, Division of Human Resource Management.
the National Science Foundation (NSF) announces the following meeting:

**Name and Committee Code:** Proposal Review Panel for Office of International Science and Engineering—PIRE: Neural Mechanisms of Reward and Decision—Reverse Site Visit (#10749).

**Date and Time:** November 15, 2018; 8:00 a.m.–5:00 p.m.

**Place:** National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

**Type of Meeting:** Part open.

**Contact Person:** Cassandra Dudka, PIRE Program Manager, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; Telephone 703/292–7250.

**Purpose of Meeting:** NSF reverse site visit to conduct a review during year 3 of the five-year award period. To conduct an in-depth evaluation of performance, to assess progress towards goals, and to provide recommendations.

**Agenda:** See attached.

**Reason for Closing:** Topics to be discussed and evaluated during closed portions of the reverse site review will include information of a proprietary or confidential nature, including technical information; and information on personnel. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.


**Crystal Robinson,**

**Committee Management Officer.**

**National Science Foundation 2415 Eisenhower Avenue Alexandria, VA 22314**

Partnerships for International Research and Education (PIRE) Reverse Site Visit Agenda

**NSF Room W2210**

**Thursday, November 15, 2018**

8:00 a.m. Panelists arrive. Coffee/light refreshments available.

8:15 a.m.–8:45 a.m. Panel Orientation—(CLOSED)

PIRE Rationale and Goals, Charge to Panel

8:45 a.m. PIIs arrive. Introductions. (OPEN)

9:00 a.m.–11:30 a.m. PIRE Project Presentation should cover the following: (OPEN)

Research

Integrating Research & Education

Students (e.g. involvement in project, recruitment, diversity)

Project Management and Communication

Evaluation & Assessment

Institutional Support

International Partnerships

11:30 a.m.–12:30 p.m. Questions and Answers

12:30 p.m.–2:00 p.m. Working Lunch—Panel Discussion—(CLOSED)

2:00 p.m.–2:30 p.m. Initial Feedback to Project Team (CLOSED)

2:30 p.m. PIRE PI and presenters are dismissed

2:30 p.m.–4:30 p.m. Panel meets for Reverse Site Visit Report Preparation—(CLOSED)

4:30 p.m.–4:45 p.m. Report presented to and discussion held with NSF staff—(CLOSED)

5:00 p.m. End of Reverse Site Visit

[BFRDoc: 2018–22848 Filed 10–18–18; 8:45 am]

**BILLING CODE 7555–01–P**

---

**NUCLEAR REGULATORY COMMISSION**

[Docket No. 72–1050; NRC–2016–0231]

Interim Storage Partners LLC’s Consolidated Interim Storage Facility

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Environmental impact statement; extension of comment period.

**SUMMARY:** On September 4, 2018, the U.S. Nuclear Regulatory Commission (NRC) published in the Federal Register a notice to reopen the scoping period on the NRC’s Environmental Impact Statement (EIS) for the Interim Storage Partners LLC (ISP) proposed consolidated interim storage facility for spent nuclear fuel, to be located on the Waste Control Specialists LLC (WCS) site in Andrews County, Texas. ISP requested on June 8, 2018, that the NRC resume its review, which had been suspended on April 18, 2017, and provided a revised license application. The NRC is extending the public scoping comment period to allow more time for members of the public to develop and submit their comments.

**DATES:** The due date of comments requested in the document published on September 4, 2018 (83 FR 44922), is extended. Comments should be filed no later than November 19, 2018.

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 on or before this date.

**ADDRESSES:** You may submit comments by any of the following methods:

- **Federal Rulemaking Website:** Go to http://www.regulations.gov and search for Docket ID NRC–2016–0231.
- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publically-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, 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. Documents related to WCS’ license application can be found under NRC Docket Number 72–1050.
- **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.
- **Project web page:** Information related to the ISP consolidated interim storage facility (CISF) project can be accessed on the NRC’s project web page at: https://www.nrc.gov/waste/spent-fuel-storage/cis/waste-control-specialist.html.

---

For further information contact:


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:**


**SUPPLEMENTARY INFORMATION:**

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0231 when contacting the NRC about the availability of information for this action. You may obtain publically-available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to http://www.regulations.gov and search for Docket ID NRC–2016–0231.
- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publically-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, 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. Documents related to WCS’ license application can be found under NRC Docket Number 72–1050.
- **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.
- **Project web page:** Information related to the ISP consolidated interim storage facility (CISF) project can be accessed on the NRC’s project web page at: https://www.nrc.gov/waste/spent-fuel-storage/cis/waste-control-specialist.html.

---

For further information contact:


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:**


**SUPPLEMENTARY INFORMATION:**

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2016–0231 when contacting the NRC about the availability of information for this action. You may obtain publically-available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to http://www.regulations.gov and search for Docket ID NRC–2016–0231.
- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publically-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, 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. Documents related to WCS’ license application can be found under NRC Docket Number 72–1050.
- **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.
- **Project web page:** Information related to the ISP consolidated interim storage facility (CISF) project can be accessed on the NRC’s project web page at: https://www.nrc.gov/waste/spent-fuel-storage/cis/waste-control-specialist.html.
B. Submitting Comments

Please include Docket ID NRC–2016–0231 in your comment submission. Comments received during this extended scoping period will be considered by the NRC in determining the scope of the EIS. Scoping comments submitted previously need not be resubmitted during this extended scoping period.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at https://www.regulations.gov/ as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Discussion

On April 28, 2016, WCS submitted a license application to NRC for a proposed CISF for spent nuclear fuel. The NRC accepted the WCS application for detailed review on January 26, 2017. On November 14, 2016 (81 FR 79531), the NRC opened the public scoping period for its EIS on the WCS license application. On April 18, 2017, WCS requested that NRC temporarily suspend its review. The EIS public scoping comment period closed on April 28, 2017.

On June 8, 2018, ISP (a joint venture between WCS and Orano CIS LLC) requested that NRC resume its detailed review and submitted a revised CISF license application. On July 19, 2018, ISP provided an update to its application. On September 4, 2018 (83 FR 44922), the NRC reopened the scoping period for its EIS, with comments to be submitted by October 19, 2018.

III. Extending Public Comment Scoping Period

The NRC is extending the public comment scoping period to November 19, 2018.

Dated at Rockville, Maryland, this 15th day of October, 2018.

For the Nuclear Regulatory Commission.

Brian W. Smith,
Acting Director, Division of Fuel Cycle Safety, Safeguards, and Environmental Review, Office of Nuclear Material Safety and Safeguards.

BILLSING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–271 and 72–59; NRC–2018–0216]

In the Matter of Entergy Nuclear Yankee, LLC; Entergy Nuclear Operations, Inc.; NorthStar Vermont Yankee LLC; NorthStar Nuclear Decommissioning Company, LLC; Vermont Yankee Nuclear Power Station

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct and indirect transfer of license; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an order approving the direct transfer of Renewed Facility Operating License No. DPR–28 for the Vermont Yankee Nuclear Power Station (VY), and its general license for the VY Independent Spent Fuel Storage Installation (ISFSI), from the currently licensed operator, Entergy Yankee Nuclear Operations, Inc. (ENOI), and currently licensed owner, Entergy Nuclear Vermont Yankee, LLC (ENVY), to NorthStar Nuclear Decommissioning Company, LLC (NorthStar NDC), and to ENVY’s successor NorthStar Vermont Yankee, LLC (NorthStar VY). This order also approves the indirect transfer of control of the license from ENVY’s Entergy parent holding and investment companies to NorthStar Decommissioning Holdings, LLC and its parents NorthStar Group Services, Inc. (NorthStar), LVI Parent Corp., and NorthStar Group Holdings, LLC. The NRC is also issuing a conforming amendment for the facility operating license for administrative purposes to reflect the approved license transfer.

The NRC confirmed that NorthStar NDC, and the entity to be named NorthStar VY, met the regulatory, legal, technical, and financial obligations necessary to qualify them as a transferor and determined that the transferor is qualified to be the holder of the license; and the transfer of the license is otherwise consistent with the applicable provisions of law, regulations, and orders issued by the Commission. The Order approving the direct transfer of the VY license to NorthStar NDC and NorthStar VY and the indirect transfer to NorthStar Decommissioning Holdings, LLC and its parents became effective on October 11, 2018.

DATES: The Order was issued on October 11, 2018, and is effective for one year.

ADDRESSES: Please refer to Docket ID NRC–2018–0216 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• Federal Rulemaking Website: Go to https://www.regulations.gov and search for Docket ID NRC–2018–0216. Address questions about Docket IDs in Regulations.gov to Jennifer Borges; telephone: 301–287–9127; email: Jennifer.Borges@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 publicly-available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, 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 license transfer Order, the NRC safety evaluation supporting the staff’s findings, and the conforming license amendment are available in ADAMS under Accession Nos. ML18248A096, ML18242A639, and ML18253A202, respectively.

• 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.


SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated at Rockville, Maryland, this 15th day of October 2018.
For the Nuclear Regulatory Commission.

John R. Tappert,
Director, Division of Decommissioning,
Uranium Recovery and Waste Programs,
Office of Nuclear Material Safety and
Safeguards.

Attachment—Order Approving the Transfer of License and Conforming Amendment

UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

(Docket Nos.: 50–271 and 72–59; License No.: DPR–28)

In the Matter of Entergy Nuclear Vermont Yankee, LLC

Entergy Nuclear Operations, Inc.

Vermont Yankee Nuclear Power Station

ORDER APPROVING THE TRANSFER OF LICENSE AND CONFORMING AMENDMENT

I.

Entergy Nuclear Operations, Inc. (ENOI), on behalf of itself and Entergy Nuclear Vermont Yankee, LLC (ENVY), are the holders of Renewed Facility Operating License No. DPR–28, which authorizes the operation of the Vermont Yankee Nuclear Power Station (VY), and the general license for the VY Independent Spent Fuel Storage Installation (ISFSI), VY permanently ceased operations on December 29, 2014. Pursuant to Sections 50.82(a)(1)(i) and (a)(1)(ii) of Title 10 of the Code of Federal Regulations (10 CFR), by letter dated January 12, 2015, ENOI certified to the NRC that it had permanently ceased operations at VY and that all fuel had been permanently removed from the reactor. Therefore, pursuant to 10 CFR 50.82(a)(2), operations at VY are no longer authorized under the 10 CFR part 50 license, and ENOI and ENVY were licensed to positions, but not use or operate, VY under Renewed Facility Operating License No. DPR–28, subject to the conditions specified therein. The VY site is located in the town of Vernon, Vermont, in Windham County on the west shore of the Connecticut River immediately upstream of the Vernon Hydroelectric Station.

II.

By letter dated February 9, 2017 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17045A140), and as supplemented by letters dated April 6, 2017 (ADAMS Accession No. ML17096A394), August 22, 2017 (ADAMS Accession No. ML17244A141), August 28, 2017 (ADAMS Accession No. ML17248A468), December 4, 2017 (ADAMS Accession No. ML17339A896), December 22, 2017 (ADAMS Accession No. ML18009A450), May 21, 2018 (ADAMS Accession No. ML18143B484), and June 26, 2018 (ADAMS
public, and that such activities will be conducted in compliance with the Commission’s regulations.

(3) The issuance of the proposed license amendment will not be inimical to the common defense and security or to the health and safety of the public.

(4) The issuance of the proposed license amendment is in accordance with 10 CFR part 51 of the Commission’s regulations, and all applicable requirements have been satisfied.

The findings set forth above are supported by an NRC safety evaluation dated October 11, 2018, which is available at ADAMS Accession No. ML18242A639.

III. Accordingly, pursuant to Sections 161b, 161i, 161o, and 184 of the AEA, 42 U.S.C. Sections 2201(b), 2201(i), 2201(o), and 2234; and 10 CFR 50.80, 10 CFR 72.50, and 10 CFR 50.90, IT IS HEREBY ORDERED that the application for the direct and indirect transfer of the license as described herein is approved for Vermont Yankee Nuclear Power Station and the ISFSI, subject to the following conditions:

(1) Prior to the closing of the license transfer, NorthStar NDC and NorthStar VY shall provide to the Directors of NRC’s Office of Nuclear Material Safety and Safeguards (NMS&SS) and Office of Nuclear Reactor Regulation (NRR) satisfactory documentary evidence that they have obtained the appropriate amount of insurance required of a licensee under 10 CFR 140.11(a)(4) and 10 CFR 50.54(w) of the Commission’s regulations, consistent with the exemptions issued to VY on April 15, 2016.

(2) NorthStar Vermont Yankee, LLC and NorthStar Nuclear Decommissioning Company, LLC shall take no action to cause NorthStar Group Services, Inc., to void, cancel, or modify the $140 million Support agreement to provide funding for Vermont Yankee as represented in the application without prior written consent of the Director of the Office of Nuclear Reactor Regulation. (3) NorthStar Vermont Yankee, LLC shall obtain a performance bond if a Settlement Agreement with the U.S. Department of Energy (DOE), on DOE reimbursements for spent fuel management expenses, is not entered into by January 1, 2022. The performance bond will be effective January 1, 2022, initially in the amount of $4.3 million, and it will be renewed annually. This amount covers the annual amount of Independent Spent Fuel Storage Installation (ISFSI) operation and maintenance (O&M) costs projected for 2022–2024. If a settlement is not reached by January 1, 2024, this amount will be increased to $9.3 million, which covers the annual amount of ISFSI O&M costs projected for years after 2024.

IT IS FURTHER ORDERED that, consistent with 10 CFR 2.1315(b), the license amendment makes changes, as indicated in Enclosure 2 to the cover letter forwarding this Order, to conform the license to reflect the subject direct and indirect license transfer, is approved. The amendment shall be issued and made effective within 30 days of the date of when the proposed direct and indirect license transfer action is completed.

IT IS FURTHER ORDERED that NorthStar NDC and NorthStar VY shall, at least 2 business days prior to closing, inform the Directors of NMSS and NRR in writing of the date of closing of the license transfer for VY and the ISFSI. Should the transfer of the license not be completed within 1 year of this Order’s date of issuance, this Order shall become null and void; provided, however, that upon written application and for good cause shown, such date may be extended by order. This Order is effective upon issuance.

For further details with respect to this Order, see the initial application dated February 9, 2017, as supplemented by letters dated April 6, 2017, August 22, 2017, August 27, 2017, December 4, 2017, December 22, 2017, May 21, 2018, and June 28, 2018, and the associated NRC safety evaluation dated October 11, 2018, which are available for public inspection at the Commission’s Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available documents are accessible electronically through ADAMS in the NRC Library at http://www.nrc.gov/reading-rm/adams.html. Persons who encounter problems with ADAMS should contact the NRC’s PDR reference staff by telephone at 1–800–397–4209 or 301–415–4737 or by e-mail to pdr.resource@nrc.gov.

DATED at Rockville, Maryland this 11th day of October 2018.

For the Nuclear Regulatory Commission.

Marc L. Dapas,
Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2018–22768 Filed 10–18–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0219]

Performance Review Boards for Senior Executive Service

AGENCY: Nuclear Regulatory Commission.

ACTION: Appointments.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has announced appointments to the NRC Performance Review Board (PRB) responsible for making recommendations on performance appraisal ratings and performance awards for NRC Senior Executives and Senior Level System employees and appointments to the NRC PRB Panel responsible for making recommendations to the appointing and awarding authorities for NRC PRB members.

DATES: October 19, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0219 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:


- 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:


SUPPLEMENTARY INFORMATION: The following individuals appointed as members of the NRC PRB are responsible for making recommendations to the appointing and awarding authorities on performance appraisal ratings and performance awards for Senior Executives and Senior Level System employees:

- Margaret M. Doane, Executive Director for Operations;
- Marian L. Zobler, General Counsel;
- Daniel H. Dorman, Deputy Executive Director for Materials, Waste, Research, State, Tribal, Compliance, Administration, and Human Capital Programs, Office of the Executive Director for Operations;
- Michael R. Johnson, Deputy Executive Director for Reactor and Preparedness Programs, Office of the Executive Director for Operations;
- Marc L. Dapas, Director, Office of Nuclear Material Safety and Safeguards;
- Frederick D. Brown, Director, Office of Nuclear Security and Incident Response;
I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0237 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- 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.

B. Submitting Comments

Please include Docket ID NRC–2018–0237 in your comment submission. The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at http://www.regulations.gov as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information. If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Introduction

The NRC is considering the issuance of an order under 10 CFR 50.80 and
72.50 approving the direct transfer of control of Oyster Creek Renewed Facility Operating License No. DPR–16, as well as the general license for the Oyster Creek ISFSI, currently held by Exelon. The transfer would be to OCEP as the licensed owner and HDI as the licensed operator. The NRC is also considering amending the renewed facility operating license and ISFSI general license for administrative purposes to reflect the proposed transfer.

Following approval of the proposed direct transfer of control of the license, OCEP would acquire ownership of the facility, and HDI would be responsible for the operation and maintenance of Oyster Creek in the permanently shutdown and defueled condition. No physical changes to the Oyster Creek facility or operational changes are being proposed in the application.

The NRC's regulations at 10 CFR 50.80 state that no license, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. The Commission will approve an application for the direct transfer of a license if the Commission determines that the proposed transferee is qualified to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission.

Before issuance of the proposed conforning license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission’s regulations.

As provided in 10 CFR 2.1315, unless otherwise determined by the Commission with regard to a specific application, the Commission has determined that any amendment to the license of a utilization facility or to the license of an ISFSI, which does no more than conform the license to reflect the transfer action involves no significant hazards consideration and no genuine issue as to whether the health and safety of the public are significantly affected. No contrary determination has been made with respect to this specific license amendment application. In light of the generic determination reflected in 10 CFR 2.1315, no public comments with respect to significant hazards considerations are being solicited, notwithstanding the general comment procedures contained in 10 CFR 50.91.

III. Opportunity To Comment

Within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted as described in the ADDRESSES section of this document.

IV. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 20 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission’s “Agency Rules of Practice and Procedure” in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC’s regulations are accessible electronically from the NRC Library on the NRC’s website at http://www.nrc.gov/reading-rm/doc-collections/cfr/. A copy of the regulations is available at the NRC’s Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (First Floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d), the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing:

1. The name, address, and telephone number of the petitioner;
2. The nature of the petitioner’s right under the Act to be made a party to the proceeding;
3. The nature and extent of the petitioner’s property, financial, or other interest in the proceeding; and
4. The possible effect of any decision or order which may be entered in the proceeding on the petitioner’s interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to all other sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements of 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party’s admitted contentions, including the opportunity to present evidence, consistent with the NRC’s regulations, policies, and procedures.

Petitions must be filed no later than 20 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the “Electronic Submissions (E-Filing)” section of this document.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner’s interest in the proceeding. The petition should be submitted to the Commission no later than 20 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the “Electronic Submissions (E-Filing)” section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2), a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with any party may, at the discretion of the presiding officer, be permitted to make
a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

V. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC’s E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at http://www.nrc.gov/site-help/e-submittals.html. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at hearing.docket@nrc.gov, or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC’s public website at http://www.nrc.gov/site-help/e-submittals/getting-started.html. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC’s public website at http://www.nrc.gov/site-help/electronic-sub-ref-mat.html. A filing is considered complete at the time the document is submitted through the NRC’s E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC’s Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC’s adjudicatory E-Filing system may seek assistance by contacting the NRC’s Electronic Filing Help Desk through the “Contact Us” link located on the NRC’s public website at http://www.nrc.gov/site-help/e-submittals.html, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC’s electronic hearing docket which is available to the public at https://adams.nrc.gov/ehd, unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC’s electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the Federal Register and served on the parties to the hearing.

For further details with respect to this application, see the application dated August 31, 2018.
VI. Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Any person who desires access to proprietary, confidential commercial information that has been redacted from the application should contact the applicant by telephoning Tamara Domeyer, Associate General Counsel for Exelon, at 630–657–3753 for the purpose of negotiating a confidentiality agreement or a proposed protective order with the applicant. If no agreement can be reached, persons who desire access to this information may file a motion with the Secretary and addressed to the Commission that requests the issuance of a protective order.

Dated at Rockville, Maryland, on October 16, 2018.

For the Nuclear Regulatory Commission.

John G. Lamb,

Senior Project Manager, Special Projects and Process Branch, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2018–22831 Filed 10–18–18; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION


New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission’s consideration concerning negotiated service agreements. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: Comments are due: October 23, 2018 and October 24, 2018.

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 further information contact section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.


Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request’s acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service’s request(s) can be accessed via the Commission’s website (http://www.prc.gov). Non-public portions of the Postal Service’s request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.

The Commission invites comments on whether the Postal Service’s request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.


II. Docketed Proceeding(s)


This Notice will be published in the Federal Register.

Stacy L. Ruble,
Secretary.

[FR Doc. 2018–22815 Filed 10–18–18; 8:45 am]
BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: Date of required notice: October 19, 2018.

FOR FURTHER INFORMATION CONTACT:
Elizabeth Reed, 202–268–3179.

Elizabeth Reed,
Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–22770 Filed 10–18–18; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: Date of required notice: October 19, 2018.

FOR FURTHER INFORMATION CONTACT:
Elizabeth Reed, 202–268–3179.

Elizabeth Reed,
Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–22774 Filed 10–18–18; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: Date of required notice: October 19, 2018.

FOR FURTHER INFORMATION CONTACT:
Elizabeth Reed, 202–268–3179.

Elizabeth Reed,
Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–22770 Filed 10–18–18; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule’s Competitive Products List.

DATES: Date of required notice: October 19, 2018.

FOR FURTHER INFORMATION CONTACT:
Elizabeth Reed, 202–268–3179.

Elizabeth Reed,
Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–22772 Filed 10–18–18; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: Date of required notice: October 19, 2018.

FOR FURTHER INFORMATION CONTACT:
Elizabeth Reed, 202–268–3179.

Elizabeth Reed,
Attorney, Corporate and Postal Business Law.

[FR Doc. 2018–22771 Filed 10–18–18; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express and Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.
ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule’s Competitive Products List.

DATES: Date of required notice: October 19, 2018.

FOR FURTHER INFORMATION CONTACT:
Elizabeth Reed, 202–268–3179.
Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the First Trust Senior Loan Fund of First Trust Exchange-Traded Fund IV

October 15, 2018.

I. Introduction

On June 27, 2018, the Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) \(^1\) and Rule 19b–4 thereunder,\(^2\) a proposed rule change relating to the First Trust Senior Loan Fund (the “Fund”) of First Trust Exchange-Traded Fund IV, the shares (“Shares”) of which have been approved by the Commission for listing and trading under Nasdaq Rule 5735 ("Managed Fund Shares"). The proposed rule change was published for comment in the Federal Register on July 17, 2018.\(^3\) On August 30, 2018, pursuant to Section 19(b)(2) of the Act,\(^4\) the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.\(^5\) On October 11, 2018, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the original filing in its entirety.\(^6\) The Commission has received no comments on the proposed rule change. This order grants approval of the proposed rule change, as modified by Amendment No. 1.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

The Commission previously approved the listing and trading of the Shares of the Fund.\(^7\) The Exchange is proposing to: (i) Amend the definition of the term "under normal market conditions;" (ii) permit the Fund to invest a limited amount of its net assets in Senior Loans\(^8\) and other floating rate loans that are in default ("Defaulted Loans"); and (iii) modify the Fund’s ability to retain various instruments that, although not specifically selected by the Adviser, may be received by the Fund under certain circumstances. Except as provided in the Exchange’s current proposal, all other representations made in the Prior Notice remain unchanged.

A. Definition of “Under Normal Market Conditions”

The Prior Notice stated that the Fund, under normal market conditions, would seek to outperform the S&P/LSTA U.S. Leveraged Loan 100 Index ("Primary Index") and the Market iBoxx USD Liquid Leveraged Loan Index ("Secondary Index") by investing at least 80% of its net assets (plus any borrowings for investment purposes) in Senior Loans. The Prior Notice defined "under normal market conditions" as follows:

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. In periods of extreme market disturbance, the Fund may take temporary defensive positions, by overweighting its portfolio in cash/cash-like instruments; however, to the extent possible, the Adviser would continue to seek to achieve the Fund’s investment objective. Specifically, the Fund would continue to invest in Senior Loans (as defined herein). In response to prolonged periods of constrained or difficult market conditions the Adviser will likely focus on investing in the largest and most liquid loans available in the market.

The Exchange proposes to amend the definition of “under normal market conditions” as follows:

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. The Fund may adopt a defensive strategy (and depart from its principal investment strategies) 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. In addition, on a temporary basis, including for defensive purposes,
during periods of extreme market disturbance and during periods of high cash inflows or outflows (i.e., rolling periods of seven calendar days during which inflows or outflows of cash, in the aggregate, exceed 10% of the Fund’s net assets as of the opening of business on the first day of such period), the Fund may depart from its principal investment strategies; for example, it may hold a higher than normal proportion of its assets in cash. Under the circumstances described in the prior two sentences, the Fund may not be able to achieve its investment objectives; however, to the extent possible, the Adviser would continue to seek to achieve the Fund’s investment objectives by continuing to invest in Senior Loans (as defined herein). In response to prolonged periods of constrained or difficult market conditions the Adviser will likely focus on investing in the largest and most liquid loans available in the market.

B. Investments in Defaulted Loans

In the Prior Notice, the Exchange represented that the Adviser does not intend to purchase Senior Loans that are in default, but the Fund may hold a Senior Loan that has defaulted subsequent to its purchase by the Fund. In discussing the Fund’s other investments, the Exchange also represented that the Fund will not invest in floating rate loans of companies whose financial condition is troubled or uncertain and that have defaulted on current debt obligations, as measured at the time of investment.

The Exchange proposes to permit the Fund to invest a limited portion of its net assets in Senior Loans and other floating rate loans that are in default. As proposed, Defaulted Loans would comprise no more than 15% of the Fund’s net assets, as determined at the time of purchase (“15% Limitation”). If, subsequent to being purchased or otherwise obtained by the Fund, a Senior Loan or other floating rate loan defaults, the Fund may continue to hold such Senior Loan or other floating rate loan without regard to the 15% Limitation; however, such Senior Loan or other floating rate loan would be considered a Defaulted Loan for purposes of determining whether the Fund’s purchase of additional Defaulted Loans would comply with the 15% Limitation.

C. Received Instruments

As described in the Prior Notice, the Fund may receive equity, warrants, corporate bonds and other such securities (collectively, “Received Instruments”) as a result of the restructuring of the debt of an issuer, or a reorganization of a senior loan or bond, or acquired together with a high yield bond or senior loan(s) of an issuer (collectively, “Received Instruments Triggers”). These investments are subject to the Fund’s investment objectives, restrictions, and strategies.

a. Received Instruments Triggers

The Exchange proposes to modify the Received Instruments Triggers to provide that the Fund may receive Received Instruments (i) in conjunction with the restructuring or reorganization, as applicable, of an issuer or any debt issued by an issuer, whether accomplished within or outside of a bankruptcy proceeding under 11 U.S.C. 101 et seq. (or any other similar statutory restructuring or reorganization proceeding) or (ii) together with one or more Senior Loans (or other debt instruments) of an issuer.

b. Equity and Equity-Like Instruments and Interests

The Prior Notice stated that except for investments in exchange-traded funds that may hold non-U.S. issues, the Fund would not otherwise invest in non-U.S. equity issues (“Non-U.S. Equity Restriction”). The Prior Notice also stated that the equity securities in which the Fund may invest would be limited to securities that trade in markets that are members of the ISG or companies that it believes have developed strong positions within their market’s pricing, profit, and other fundamental characteristics. The Fund would not otherwise invest in non-U.S. equity issues, as measured at the time of investment.

The Exchange proposes to permit the Fund to invest a limited portion of its net assets in foreign equity issues as a result of the foreign issuer’s restructuring and reorganization, or a reorganization of a senior loan or bond, or acquired together with a high yield bond or senior loan(s) of an issuer (collectively, “Received Instruments Triggers”). These investments are subject to the Fund’s investment objectives, restrictions, and strategies.

c. Convertible Securities/Debt Instruments

In the Prior Notice, the Exchange represented that each of the Fund’s Senior Loan investments was expected to have no less than $250 million par outstanding (“Par Amount Limitation”).

The Exchange also proposes to make conforming changes to the descriptions in the Prior Notice regarding the characteristics of borrowers that will be included in the Fund. In particular, the Exchange proposes the following revised “Credit Metrics Representation”: “As a general matter, the Fund will include borrowers that the Adviser believes have strong credit metrics, based on its evaluation of cash flows, collateral coverage and management teams.” The Exchange also proposes the following revised “Senior Loan/Other Debt Representations”: “As a general matter, the Adviser intends to invest in Senior Loans or other debt of companies that it believes have developed strong positions within their market’s pricing, profit, and other fundamental characteristics. The Exchange also proposes to permit the Fund to invest a limited portion of its net assets in foreign equity issues as a result of the foreign issuer’s restructuring and reorganization, or a reorganization of a senior loan or bond, or acquired together with a high yield bond or senior loan(s) of an issuer (collectively, “Received Instruments Triggers”). These investments are subject to the Fund’s investment objectives, restrictions, and strategies.

The Exchange also proposes to add the following revised “Senior Loan/Other Debt Representations”: “As a general matter, the Adviser intends to invest in Senior Loans or other debt of companies that it believes have strong credit metrics, based on its evaluation of cash flows, collateral coverage and management teams.” The Exchange also proposes the following revised “Junior Loan/Other Debt Representations”: “As a general matter, the Adviser intends to focus on investments in which the Senior Loans or other debt of a target company has an experienced management team with an established track record of success. The Adviser will generally require companies to have in place proper incentives to align management’s goals with the Fund’s goals.”
The Exchange also represented that the Fund would not typically invest in convertible securities, but that should the Fund make such investments, the Adviser would direct the Fund to divest any converted equity security as soon as practicable (“Convertible Securities Restriction”). The Exchange proposes to permit the Fund to retain Received Instruments in its portfolio, without regard to the Par Amount Representation or the Convertible Securities Restriction. Further, the Exchange proposes to permit the Fund to continue to retain in its portfolio Received Instruments that are convertible securities after such securities have converted (i.e., as Equity-Based Received Instruments) without regard to the Convertible Securities Restriction, the Non-U.S. Equity Restriction, or the ISG Restriction. Consistent with the Prior Release, Received Instruments that are convertible securities, bonds, loans, or other debt instruments of any type may be issued by U.S. and/or non-U.S. issuers. As noted above, the Fund would not hold more than 20% of its net assets in the aggregate in (i) Received Instruments that are not Senior Loans and (ii) Received Instruments that are Senior Loans and do not satisfy the Par Amount Representation.

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange. In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,16 which requires, among other things, that the Exchange’s rules be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes that the proposed definition of “under normal market conditions” would provide flexibility under certain conditions where the Adviser may find that it is appropriate for the Fund to depart from its principal investment strategies, which could potentially help the Fund to mitigate risks that may accompany these conditions.9 With respect to the aspect of the proposal that would permit the Fund to invest a portion of its net assets in Defaulted Loans, the Commission believes that the proposal would provide the Adviser with additional flexibility, but would be limited in scope. As discussed above, Defaulted Loans would be subject to the 15% Limitation. If, subsequent to being purchased or otherwise obtained by the Fund, a Senior Loan or other floating rate loan defaults, the Fund may continue to hold such Senior Loan or other floating rate loan without regard to the 15% Limitation; however, such Senior Loan or other floating rate loan would be considered a Defaulted Loan for purposes of determining whether the Fund’s purchase of additional Defaulted Loans would comply with the 15% Limitation.18

17 In particular, the proposal would provide flexibility to the Adviser when the Adviser believes that the securities in which the Fund normally invests have elevated risks due to political or economic factors, in other extraordinary circumstances, and during periods of high cash flows or outflows. The Commission notes that the proposed definition is consistent with the definitions from other recently approved proposals. See Securities Exchange Act Release Nos. 80745 (May 23, 2017), 81 FR 3252 (May 30, 2017) (SR–NASDAQ–2017–003) (order approving listing and trading of First Trust California Municipal High Income ETF) and 78913 (September 23, 2016), 81 FR 69109 (October 5, 2016) (SR–NASDAQ–2016–002) (order approving listing and trading of First Trust Municipal High Income ETF).


As discussed above, the Exchange also proposes to amend the Received Instruments Triggers and to permit the Fund to retain a limited amount of Received Instruments. The Commission notes that the Fund’s ability to retain Received Instruments would be limited in scope. As discussed above, the Fund’s aggregate holdings in (a) Received Instruments that are not Senior Loans and (b) Received Instruments that are Senior Loans and do not satisfy the Par Amount Representation would be limited to 20% of the Fund’s net assets.19 The Commission notes that the Exchange does not propose to change the Fund’s investment objectives and, except as provided in the current proposal, all other representations made in the Prior Notice would remain unchanged. The Commission notes that, notwithstanding the proposed changes, the Exchange anticipates that the Fund, in accordance with its principal investment strategy, would continue to invest approximately 50% to 75% of its net assets in Senior Loans that are eligible for inclusion in and meet the liquidity thresholds of the Primary Index and/or the Secondary Index.20 Moreover, the aggregate amount of the Fund’s net assets permitted to be held in illiquid securities (calculated at the time of investment), including Rule 144A securities, junior subordinated loans, and unsecured loans deemed illiquid by the Adviser, would continue to be limited to 15%.21 In addition, except for the generic listing standards

Nasdaq Rule 5705(b)(4)(A)(vi) provided the entities that would not meet the criteria set forth in these conditions.17

The Commission notes that, in particular, the proposal would provide additional flexibility to the Adviser when the Adviser believes that the securities in which the Fund normally invests have elevated risks due to political or economic factors, in other extraordinary circumstances, and during periods of high cash flows or outflows. The Commission notes that the proposed definition is consistent with the definitions from other recently approved proposals. See Securities Exchange Act Release Nos. 80745 (May 23, 2017), 81 FR 3252 (May 30, 2017) (SR–NASDAQ–2017–003) (order approving listing and trading of First Trust California Municipal High Income ETF) and 78913 (September 23, 2016), 81 FR 69109 (October 5, 2016) (SR–NASDAQ–2016–002) (order approving listing and trading of First Trust Municipal High Income ETF).


19 As a result, although it is possible that the Fund’s holdings may include certain Received Instruments that are Senior Loans and do not satisfy the Par Amount Representation, at least 80% of the Fund’s net assets will be comprised of Senior Loans that do satisfy the Par Amount Representation. Similarly, as discussed above, Equity-Based Received Instruments would comprise no more than 20% of the Fund’s net assets and the Adviser expects that, generally, over time, significantly less than 20% of the Fund’s net assets would be comprised of Equity-Based Received Instruments.

The Exchange provided descriptions of the eligibility criteria for the Primary Index and the Secondary Index in the Prior Notice and updates certain of those descriptions in the current proposal.

21 The Exchange also represents that the proposed changes would not conflict with the Fund’s investment objectives, or overall investment strategies, or be inconsistent with the Adviser’s overall approach to managing the Fund. According to the Exchange, in selecting securities for the Fund, the Adviser would continue to seek to construct a portfolio of loans that it believes is less volatile than the general loan market. In addition, when making investments, the Adviser would continue to seek to maintain appropriate liquidity and price transparency for the Fund, and the key considerations of portfolio construction would continue to include liquidity, diversification, and relative value.
under Nasdaq Rule 5735(b)(1) and as otherwise provided in the current proposal, the Fund and the Shares would continue to comply with the requirements applicable to Managed Fund Shares under Nasdaq Rule 5735.

The Commission also finds that the proposal is consistent with Section 11A(a)(1)(C)(iii) of the Act, which sets forth Congress’s finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and the public of information with respect to quotations for and transactions in securities. As proposed, intra-day executable price quotations for the Senior Loans, fixed income securities, and other assets (including any Received Instruments and Defaulted Loans) held by the Fund would be available from major broker-dealer firms and/or market data vendors (and/or, if applicable, on the exchange on which they are traded). Intra-day price information for the holdings of the Fund would be available through subscription services, such as Markit, Bloomberg, and Thomson Reuters, which can be accessed by authorized participants and other investors, and/or from independent pricing services.

On each business day, before commencement of trading in Shares in the Regular Market Session on the Exchange, the Fund would continue to disclose on www.ftportfolios.com the Disclosed Portfolio (as defined in Nasdaq Rule 5735(c)(2)) that will form the basis for the Fund’s calculation of net asset value (“NAV”) at the end of the business day. NAV per Share would continue to be calculated daily, and the NAV and the Disclosed Portfolio would continue to be made available to all market participants at the same time. Further, the Intraday Indicative Value (as defined in Nasdaq Rule 5735(c)(3)) for the Fund would continue to be widely disseminated by one or more major market data vendors and broadly displayed at least every 15 seconds during the Regular Market Session.

In support of this proposal, the Exchange also represents that trading in the Shares will be subject to the existing trading surveillances, administered by both the Exchange and 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, and these procedures are adequate to properly monitor trading in the Shares and the exchange-listed shares held by the Fund (including exchange-listed Equity-Based Received Instruments (if any) and any other exchange-listed equity securities) with other markets and other entities that are members of ISG. FINRA and the Exchange both may obtain trading information regarding trading in the Shares and such exchange-listed instruments held by the Fund from markets and other entities that are members of ISG, which include securities exchanges. The Exchange may also obtain information regarding trading in the Shares and such exchange-listed instruments held by the Fund from markets and other entities with which it has in place a comprehensive surveillance sharing agreement. Moreover, FINRA, on behalf of the Exchange, would 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. The Exchange represents that all statements and representations made in the filing regarding (a) the description of the portfolio or reference assets, (b) limitations on portfolio holdings or reference assets, (c) dissemination and availability of the reference asset or intraday indicative values, or (d) the applicability of Exchange listing rules shall constitute continued listing requirements for listing the Shares on the Exchange. In addition, the issuer has represented to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under the Nasdaq 5800 Series.

This approval order is based on all of the Exchange’s representations, including those set forth above and in Amendment No. 1. For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act and Section 11A(a)(1)(C)(iii) of the Act and the rules and regulations thereunder applicable to a national securities exchange.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (SR–NASDAQ–2018–050), as modified by Amendment No. 1 be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.

Eduardo A. Aleman,
Assistant Secretary.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–348, OMB Control No. 3235–0394]

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension: Rule 15g–5

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (“PRA”) (44 U.S.C. 3501 et seq.), the Securities and Exchange Commission (“Commission”) has submitted to the Office of Management and Budget (“OMB”) a request for approval of extension of the previously approved Commission’s view that “monitor” and “surveil” both mean ongoing oversight of compliance with the continued listing requirements. Therefore, the Commission does not view “monitor” as a more or less stringent obligation than “surveil” with respect to the continued listing requirements.


24 The Exchange states that FINRA surveils trading on the Exchange pursuant to a regulatory services agreement, and the Exchange is responsible for FINRA’s performance under this regulatory services agreement.

25 The Commission notes that certain proposals for the listing and trading of exchange-traded products include a representation that the exchange will “surveil” for compliance with the continued listing requirements. See, e.g., Securities Exchange Act Release No. 77499 (April 1, 2016), 81 FR 20428, 20432 (April 7, 2016) (SR–BATS–2016–04). In the context of this representation, it is the


Rule 15g–5 requires brokers and dealers to disclose to customers the amount of compensation to be received by their sales agents in connection with penny stock transactions. The purpose of the rule is to increase the level of disclosure to investors concerning penny stocks generally and specific penny stock transactions.

The Commission estimates that approximately 195 broker-dealers will spend an average of 87 hours annually to comply with the rule. Thus, the total compliance burden is approximately 16,965 burden-hours per year.

Rule 15g–5 contains record retention requirements. Compliance with the rule is mandatory.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information directly to investors concerning penny stocks generally and specific penny stock transactions.

The public may view background documentation for this information collection at the following website: www.reginfo.gov. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503 or by sending an email to: Shagufa_Ahmed@omb.eop.gov; and (ii) Charles Riddle, Acting Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or by sending an email to PRA_Mailbox@sec.gov. Comments must be submitted within 30 days of this notice.


Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018–22781 Filed 10–18–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations;
National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Clearing Agency Policy on Capital Requirements and the Clearing Agency Capital Replenishment Plan

October 15, 2018.

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 October 4, 2018, National Securities Clearing Corporation (“NSCC”) 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 clearing agency. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act \(^3\) and Rule 19b–4(f)(4) thereunder.\(^4\) The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to (i) the Clearing Agency Policy on Capital Requirements (“Capital Policy” or “Policy”) of NSCC and its affiliates, The Depository Trust Company (“DTC”) and Fixed Income Clearing Corporation (“FICC,” and together with DTC and NSCC, the “Clearing Agencies”); and (ii) the Clearing Agency Capital Replenishment Plan (“Capital Replenishment Plan” or “Plan”) of the Clearing Agencies. In particular, the proposed revisions to the Capital Policy and Capital Replenishment Plan would (1) correct typographical errors and make other technical revisions to correct and simplify statements in the Policy and Plan; (2) replace references in the Policy and Plan to the “Credit Risk Capital Requirement” with the “Corporate Contribution;” and (3) update references in the Policy to the Recovery & Wind-down Plans of each of the Clearing Agencies, which were recently adopted by the Clearing Agencies, as described in greater detail below.

\(^1\) 15 U.S.C. 78a(b)(1).

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Clearing Agencies are proposing to revise the Capital Policy and Capital Replenishment Plan, which were adopted by the Clearing Agencies in July 2017\(^5\) and are maintained by the Clearing Agencies in compliance with Rule 17Ad–22(e)(15) under the Act.\(^6\)

Overview of the Capital Policy and Capital Replenishment Plan

The Capital Policy sets forth the manner in which each Clearing Agency identifies, monitors, and manages its general business risk with respect to the requirement to hold sufficient liquid net assets (“LNA”) funded by equity to cover potential general business losses so the Clearing Agency can continue operations and services as a going concern if such losses materialize.\(^7\) The amount of LNA funded by equity to be held by each of the Clearing Agencies for this purpose is defined in the Policy as the General Business Risk Capital Requirement. The Policy provides that the General Business Risk Requirement is calculated for each Clearing Agency as the greater of three separate calculations—(1) an amount based on that Clearing Agency’s general business risk profile (“Risk-Based Capital Requirement”), (2) an amount based on the time estimated to execute a recovery or orderly wind-down of the critical operations of that Clearing Agency (“Recovery/Wind-down Capital Requirement”), and (3) an amount based on an analysis of that Clearing Agency’s estimated operating expenses for a six month period (“Operating Expense Capital Requirement”). On an annual basis, each of these three capital

\(^6\) 17 CFR 240.17Ad–22(e)(15).
\(^7\) Id.
requirements are measured, and the General Business Risk Capital Requirement for each Clearing Agency are determined as the greatest of these calculations.

Currently, the Capital Policy also addresses how each Clearing Agency maintains a portion of retained earnings as LNA funded by equity as its Credit Risk Capital Requirement, as a part of its management of credit risk and pursuant to their respective rules. These resources are maintained to address losses due to a participant default, and are held in addition to the LNA funded by equity held by each of the Clearing Agencies as its General Business Risk Capital Requirement. The Capital Policy describes how each Clearing Agency’s General Business Risk Capital Requirement and Credit Risk Capital Requirement fit within the Clearing Agencies’ Capital Framework, where the Total Capital Requirement of each Clearing Agency is calculated as the sum of its General Business Risk Capital Requirement and Credit Risk Capital Requirement.

The Policy also provides a plan for the replenishment of capital through the Capital Replenishment Plan. The Capital Replenishment Plan was adopted by the Clearing Agencies as a plan for the replenishment of capital by each Clearing Agency should its equity fall close to or below the amount being held as its Total Capital Requirement pursuant to the Capital Policy. The Capital Replenishment Plan identifies the circumstances that would trigger implementation of the Plan; the roles, responsibilities, and guiding principles for implementation of the Plan; and an overview and description of each of the tools that may be used to replenish capital.

Proposed Revisions to the Capital Policy and Capital Replenishment Plan

As described in greater detail below, the Clearing Agencies are proposing to make certain revisions to the Capital Policy and Capital Replenishment Plan. First, the proposed revisions would correct typographical errors and make other technical revisions to correct and simplify statements in the Capital Policy and Capital Replenishment Plan. Second, the proposed revisions would replace references to the “Credit Risk Capital Requirement” with “Corporate Contribution.” This proposed change would reflect the implementation of recent revisions to the Clearing Agencies’ Rules regarding allocation of losses. Finally, the proposed revisions would update the description of the calculation of the Recovery/Wind-down Capital Requirement in the Capital Policy to clarify that the Recovery & Wind-down Plans of each of the Clearing Agencies have been adopted by the Clearing Agencies.

These proposed revisions are designed to enhance the clarity of the Policy and Plan and help ensure that they continue to operate as intended.

1. Technical Revisions

NSCC is proposing technical revisions to the descriptions within the Capital Policy and Capital Replenishment Plan that would correct typographical errors, including, for example, removing a phrase that was incorrectly repeated in the same sentence. These revisions would also correct an error in Section 3 of the Policy, where the document was incorrectly referred to as the Plan.

Such revisions would also update the documents. For example, the proposed changes would replace references in the Capital Policy and Capital Replenishment Plan to the Finance/Capital Committee of the Boards, which was disbanded September 2017, with the Boards, which has taken on the responsibilities of this Committee set forth in the Policy and Plan. These revisions would also include updating the Capital Replenishment Plan to revise the name of the “Capital Contributions to DTCC Subsidiaries and Joint Ventures Policy” to the new name of this document, the “Capital Contributions Policy.”

Finally, the proposed revisions would also simplify the descriptions in these documents. For example, these revisions would add a defined term for the Clearing Agencies’ Rules to the Policy in order to simplify references to such rules and procedures in this document.

2. Addition of Corporate Contribution

The proposed revisions would also replace references in the Capital Policy and Capital Replenishment Plan to the “Credit Risk Capital Requirement” with the “Corporate Contribution.” Currently, the Capital Policy describes how each Clearing Agency maintains a portion of retained earnings as LNA funded by equity as its Credit Risk Capital Requirement, in accordance with their respective Rules. Recently, the Clearing Agencies implemented revisions to their respective Rules to enhance the process by which they may allocate losses to their participants if the size of the losses exceed their prefunded resources. Such revisions included an amendment to the calculation and application of the amount of LNA funded by equity that are currently referred to in the Capital Policy and Capital Replenishment Plan as the Credit Risk Capital Requirement.

Specifically, the NSCC Rules previously provided that NSCC would contribute no less than 25 percent of its retained earnings (or such higher amount as the NSCC Board of Directors shall determine) to a loss or liability as the result of the failure of a defaulting member that is not satisfied by the defaulting member’s Clearing Fund deposit. Pursuant to these recent changes, the NSCC Rules provide that an amount equal to 50 percent of NSCC’s General Business Risk Capital Requirement (as such amount is defined in the Capital Policy), or such greater amount as the NSCC Board of Directors may determine, (“Corporate Contribution”) may be used to address unsatisfied losses or liabilities arising either from a member default or a non-default event. The Corporate Contribution applied to any losses arising from events that may occur during the next 250 business days would be reduced to the remaining unused portion of Corporate Contribution, if any.

The amendments to the calculation and application of the resources that are now referred to as the Corporate Contribution did not change how these resources were described within the Policy or the Plan. The Corporate Contribution continues to represent resources maintained by the Clearing

---

8 LNA funded by equity held as the Clearing Agencies’ Credit Risk Capital Requirement is held in addition to resources held by the Clearing Agencies for credit risk in compliance with Rule 17Ad–22(e)(4) under the Act and in addition to resources held by the Clearing Agencies for liquidity risk in compliance with Rule 17Ad–22(e)(7). 17 CFR 240.17Ad–22(e)(4), (7).


12 This document is an internal policy that governed how the Depository Trust & Clearing Corporation may invest capital in its subsidiaries, including the Clearing Agencies, as well as affiliated joint ventures and non-affiliated companies.

13 Supra note 10.

14 See supra notes 9 and 10.
Agencies to address losses due to a participant default, as a part of their management of credit risk. These resources also are still held in addition to the LNA funded by equity held by each of the Clearing Agencies as its General Business Risk Capital Requirement.

Therefore, the Capital Policy and Capital Replenishment Plan would be revised to replace references to the Credit Risk Capital Requirement with references to the Corporate Contribution, and no other changes are needed to the description of this amount.

3. Update References to the Recovery & Wind-Down Plans of the Clearing Agencies

The proposed revisions would also update the Capital Policy to make clear that the Recovery & Wind-down Plans of the Clearing Agencies have been adopted by the Clearing Agencies. Such references are currently made in connection with the description of the calculation of the Recovery/Wind-down Capital Requirement.

The Recovery/Wind-down Capital Requirement is an amount based on the time estimated to execute a recovery or orderly wind-down of the critical operations of that Clearing Agency and is used by the Clearing Agencies to determine their General Business Risk Capital Requirement. Each of the Clearing Agencies recently adopted a Recovery & Wind-down Plan, which provides plans for the recovery and orderly wind-down of each of the Clearing Agencies necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses. The Recovery & Wind-down Plans each include an analysis of the calculation of the Recovery/Wind-down Capital Requirement, based on the formula that is set forth in the Capital Policy.

The Clearing Agencies are proposing to revise the Capital Policy to make clear that the Recovery & Wind-down Plans have now been adopted by the Clearing Agencies.

2. Statutory Basis

The Clearing Agencies believe that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing

agency. In particular, the Clearing Agencies believe that the Capital Policy and the Capital Replenishment Plan are both consistent with Section 17A(b)(3)(F) of the Act and Rule 17Ad–22(e)(15) under the Act, for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of the Clearing Agencies be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control or for which it is responsible. Together, the Capital Policy and the Capital Replenishment Plan are designed to ensure that each of the Clearing Agencies hold sufficient LNA funded by equity to cover potential general business losses so that it can continue the prompt and accurate clearance and settlement of securities transactions and can continue to assure the safeguarding of securities and funds which are in its custody or control or for which it is responsible if those losses materialize. By correcting errors and updating the Capital Policy and Capital Replenishment Plan to be consistent with recent changes implemented by the Clearing Agencies, the proposed revisions would allow the Clearing Agencies to maintain these documents to operate in the way they were intended. Therefore, such proposed revisions would be consistent with the requirements of Section 17A(b)(3)(F) of the Act.

Rule 17Ad–22(e)(15) requires the Clearing Agencies to establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor, and manage their respective general business risk and hold sufficient liquid net assets funded by equity to cover potential general business losses so that the Clearing Agencies can continue operations and services as a going concern if those losses materialize. As originally implemented, the Capital Policy and the Capital Replenishment Plan were designed to meet the requirements of Rule 17Ad–22(e)(15) under the Act. As stated above, the proposed revisions would update the Capital Policy and Capital Replenishment Plan to be consistent with recent changes implemented by the Clearing Agencies.

In this way, the proposed changes would allow the Clearing Agencies to maintain these documents in a way that to meet these requirements. Therefore, such proposed revisions would be consistent with the requirements of Rule 17Ad–22(e)(15) under the Act.

(B) Clearing Agency’s Statement on Burden on Competition

Each of the Clearing Agencies believes that none of the proposed revisions to the Capital Policy and the Capital Replenishment Plan would have any impact, or impose any burden, on competition. The Policy and the Plan are maintained by the Clearing Agencies in order to satisfy their regulatory requirements and generally reflect internal tools and procedures. Tools and procedures that have a direct impact on the rights, responsibilities or obligations of members or participants of the Clearing Agencies are reflected in the Clearing Agencies’ Rules. Accordingly, the Capital Policy and Capital Replenishment Plan themselves are documents that enhance the Clearing Agencies’ regulatory compliance and internal management and do not have any impact, or impose any burden, on competition.

The proposed revisions to correct and update the Capital Policy and Capital Replenishment Plan would not affect any changes on the fundamental purpose or operation of these documents and, as such, would also not have any impact, or impose any burden, on competition.

(C) Clearing Agency’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Clearing Agencies have not solicited or received any written comments relating to this proposal. The Clearing Agencies will notify the Commission of any written comments received by the Clearing Agencies.

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) of the Act and paragraph (f) of Rule 19b–4 thereunder. 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.

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–NSCC–2018–008 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–NSCC–2018–008. 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 website (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 website 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 NSCC and on DTCC’s website (http://www.dtcc.com/legal/sec-rule-filings.aspx). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NSCC–2018–008 and should be submitted on or before November 9, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.\(^27\)

Eduardo A. Aleman,
Assistant Secretary.

[FR Doc. 2018–22780 Filed 10–18–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Clearing Agency Policy on Capital Requirements and the Clearing Agency Capital Replenishment Plan

October 15, 2018.

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 October 4, 2018, Fixed Income Clearing Corporation (“FICC”) 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 clearing agency. FICC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act\(^3\) and Rule 19b–4(f)(4) thereunder.\(^4\) The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to (i) the Clearing Agency Policy on Capital Requirements ("Capital Policy” or “Policy”) of FICC and its affiliates, The Depository Trust Company ("DTCC") and National Securities Clearing Corporation ("NSCC," and together with DTCC and FICC, the “Clearing Agencies”); and (ii) the Clearing Agency Capital Replenishment Plan ("Capital Replenishment Plan” or “Plan”) of the Clearing Agencies. In particular, the proposed revisions to the Capital Policy and Capital Replenishment Plan would (1) correct typographical errors and make other technical revisions to correct and simplify statements in the Policy and Plan; (2) replace references in the Policy and Plan to the “Credit Risk Capital Requirement” with the “Corporate Contribution;” and (3) update references in the Policy to the Recovery & Wind-down Plans of each of the Clearing Agencies, which were recently adopted by the Clearing Agencies, as described in greater detail below.

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Clearing Agencies are proposing to revise the Capital Policy and Capital Replenishment Plan, which were adopted by the Clearing Agencies in July 2017\(^5\) and are maintained by the Clearing Agencies in compliance with Rule 17Ad–22(e)(15) under the Act.\(^6\)

Overview of the Capital Policy and Capital Replenishment Plan

The Capital Policy sets forth the manner in which each Clearing Agency identifies, monitors, and manages its general business risk with respect to the requirement to hold sufficient liquid net assets (“LNA”) funded by equity to cover potential general business losses so the Clearing Agency can continue operations and services as a going concern if such losses materialize.\(^7\) The amount of LNA funded by equity to be held by each of the Clearing Agencies for this purpose is defined in the Policy as the General Business Risk Capital Requirement. The Policy provides that the General Business Risk Requirement is calculated for each Clearing Agency as the greatest of three separate calculations—(1) an amount based on that Clearing Agency’s general business risk profile ("Risk-Based Capital Requirement"); (2) an amount based on

---

\(^6\) 17 CFR 240.17Ad–22(e)(15).
\(^7\) Id.


\(^5\) Id.

the time estimated to execute a recovery or orderly wind-down of the critical operations of that Clearing Agency ("Recovery/Wind-down Capital Requirement"). and (3) an amount based on an analysis of that Clearing Agency’s estimated operating expenses for a six month period ("Operating Expense Capital Requirement"). On an annual basis, each of these three capital requirements are measured, and the General Business Risk Capital Requirement for each Clearing Agency are determined as the greatest of these calculations.

Currently, the Capital Policy also addresses how each Clearing Agency maintains a portion of retained earnings as LNA funded by equity as its Credit Risk Capital Requirement, as a part of its management of credit risk 2 and pursuant to their respective rules. 3 These resources are maintained to address losses due to a participant default, and are held in addition to the LNA funded by equity held by each of the Clearing Agencies as its General Business Risk Capital Requirement. The Capital Policy describes how each Clearing Agency’s General Business Risk Capital Requirement and Credit Risk Capital Requirement fit within the Clearing Agencies’ Capital Framework, where the Total Capital Requirement of each Clearing Agency is calculated as the sum of its General Business Risk Capital Requirement and Credit Risk Capital Requirement.

The Policy also provides a plan for the replenishment of capital through the Capital Replenishment Plan. The Capital Replenishment Plan was adopted by the Clearing Agencies as a plan for the replenishment of capital by each Clearing Agency should its equity fall close to or below the amount being held as its Total Capital Requirement pursuant to the Capital Policy. The Capital Replenishment Plan identifies the circumstances that would trigger implementation of the Plan; the roles, responsibilities, and guiding principles for implementation of the Plan; and an overview and description of each of the tools that may be used to replenish capital.

Proposed Revisions to the Capital Policy and Capital Replenishment Plan

As described in greater detail below, the Clearing Agencies are proposing to make certain revisions to the Capital Policy and Capital Replenishment Plan. First, the proposed revisions would correct typographical errors and make other technical revisions to correct and simplify statements in the Capital Policy and Capital Replenishment Plan. Second, the proposed revisions would replace references to the “Credit Risk Capital Requirement” with “Corporate Contribution.” This proposed change would reflect the implementation of recent revisions to the Clearing Agencies’ Rules regarding allocation of losses. 4 Finally, the proposed revisions would update the description of the calculation of the Recovery/Wind-down Capital Requirement in the Capital Policy to clarify that the Recovery & Wind-down Plans of each of the Clearing Agencies have been adopted by the Clearing Agencies. 5

These proposed revisions are designed to enhance the clarity of the Policy and Plan and help ensure that they continue to operate as intended.

1. Technical Revisions

FICC is proposing technical revisions to the descriptions within the Capital Policy and Capital Replenishment Plan that would correct typographical errors, including, for example, removing a phrase that was incorrectly repeated in the same sentence. These revisions would also correct an error in Section 3 of the Policy, where the document was incorrectly referred to as the Plan.

Such revisions would also update the documents. For example, the proposed changes would replace references in the Capital Policy and Capital Replenishment Plan to the Finance/ Capital Committee of the Boards, which was disbanded September 2017, with the Boards, which has taken on the responsibilities of this Committee set forth in the Policy and Plan. These revisions would also include updating the Capital Replenishment Plan to revise the name of the “Capital Contributions to DTCC Subsidiaries and Joint Ventures Policy” to the new name of this document, the “Capital Contributions Policy.” 6

Finally, the proposed revisions would also simplify the descriptions in these documents. For example, these revisions would add a defined term for the Clearing Agencies’ Rules to the Policy in order to simplify references to such rules and procedures in this document.

2. Addition of Corporate Contribution

The proposed revisions would also replace references in the Capital Policy and Capital Replenishment Plan to the “Credit Risk Capital Requirement” with the “Corporate Contribution.” Currently, the Capital Policy describes how each Clearing Agency maintains a portion of retained earnings as LNA funded by equity as its Credit Risk Capital Requirement, in accordance with their respective Rules. Recently, the Clearing Agencies implemented revisions to their respective Rules to enhance the process by which they may allocate losses to their participants if the size of the losses exceed their prefunded resources. 7 Such revisions included an amendment to the calculation and application of the amount of LNA funded by equity that are currently referred to in the Capital Policy and Capital Replenishment Plan as the Credit Risk Capital Requirement.

Specifically, the GSD Rules and MBSD Rules previously provided that FICC would contribute up to 25 percent of its retained earnings (or such higher amount as the FICC Board of Directors shall determine) to a loss or liability as the result of the failure of a defaulting member that is not satisfied by the defaulting member’s Clearing Fund deposit. Pursuant to these recent changes, the GSD Rules and MBSD Rules provide that an amount equal to 50 percent of FICC’s General Business Risk Capital Requirement (as such amount is defined in the Capital Policy), or such greater amount as the FICC Board of Directors may determine, (“Corporate Contribution”) may be used to address unsatisfied losses or liabilities arising either from a member default or a non-default event. The Corporate Contribution applied to any losses arising from events that may occur during the next 250 business days would be reduced to the remaining

---

2 LNA funded by equity held as the Clearing Agencies’ Credit Risk Capital Requirement is held in addition to resources held by the Clearing Agencies for credit risk in compliance with Rule 17Ad–22(e)(4) under the Act and in addition to resources held by the Clearing Agencies for liquidity risk in compliance with Rule 17Ad–22(e)(7). 17 CFR 240.17Ad–22(e)(4), 17.


7 Supra note 10.
The Clearing Agencies are proposing to revise the Capital Policy to make clear that the Recovery & Wind-down Plans have now been adopted by the Clearing Agencies.

2. Statutory Basis

The Clearing Agencies believe that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, the Clearing Agencies believe that the Capital Policy and the Capital Replenishment Plan are both consistent with Section 17A(b)(3)(F) of the Act and Rule 17Ad–22(e)(15) under the Act, for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of the Clearing Agencies be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the Clearing Agency or for which it is responsible. Together, the Capital Policy and the Capital Replenishment Plan are designed to ensure that each of the Clearing Agencies hold sufficient LNA funded by equity to cover potential general business losses so that it can continue the prompt and accurate clearance and settlement of securities transactions and can continue to assure the safeguarding of securities and funds which are in its custody or control or for which it is responsible if those losses materialize. By correcting errors and updating the Capital Policy and Capital Replenishment Plan to be consistent with recent changes implemented by the Clearing Agencies, the proposed revisions would allow the Clearing Agencies to maintain these documents in a way that to meet these requirements. Therefore, such proposed revisions would be consistent with the requirements of Rule 17Ad–22(e)(15) under the Act.

(B) Clearing Agency’s Statement on Burden on Competition

Each of the Clearing Agencies believes that none of the proposed revisions to the Capital Policy and the Capital Replenishment Plan would have any impact, or impose any burden, on competition. The Policy and the Plan are maintained by the Clearing Agencies in order to satisfy their regulatory requirements and generally reflect internal tools and procedures. Tools and procedures that have a direct impact on the rights, responsibilities or obligations of members or participants of the Clearing Agencies are reflected in the Clearing Agencies’ Rules. Accordingly, the Capital Policy and Capital Replenishment Plan themselves are documents that enhance the Clearing Agencies’ regulatory compliance and internal management and do not have any impact, or impose any burden, on competition.

The proposed revisions to correct and update the Capital Policy and Capital Replenishment Plan would not affect any changes on the fundamental purpose or operation of these documents and, as such, would also not have any impact, or impose any burden, on competition.

(C) Clearing Agency’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Clearing Agencies have not solicited or received any written comments relating to this proposal. The Clearing Agencies will notify the Commission of any written comments received by the Clearing Agencies.

14 See supra notes 9 and 10.
15 As noted above, unlike the resources referred to in the Policy and Plan as the Credit Risk Capital Requirement, the Corporate Contribution would also be available to the Clearing Agencies to address losses due to events other than a participant default.
16 Supra note 11.
17 Id.
19 17 CFR 240.17Ad–22(e)(15).
21 Id.
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) of the Act, 15 U.S.C. 78s(b)(3)(A), and paragraph (f) of Rule 19b–4 thereunder. 26 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.

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–FICC–2018–009 on the subject line.

Paper Comments
- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–FICC–2018–009. 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 website (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 website 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 FICC and on DTCC’s website (http://dtcc.com/legal/sec-rule-filings.aspx). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FICC–2018–009 and should be submitted on or before November 9, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 27

Eduardo A. Aleman, Assistant Secretary.

[FR Doc. 2018–22778 Filed 10–18–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delete Current Rules on Arbitration, Under Chapter 18

October 15, 2018.

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 October 9, 2018, Nasdaq GEMX, LLC (“GEMX” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “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 delete the current rules on arbitration (“Current Arbitration Rules”), under Chapter 18, and incorporate by reference The Nasdaq Stock Market LLC’s (“Nasdaq”) rules on arbitration at General 6 (“Proposed Arbitration Rules”), into General 6 of the Exchange’s rulebook (“Rulebook”) shell structure. 3

3 Recently, the Exchange added a shelf structure to its Rulebook with the purpose of improving efficiency and readability and to align its rules closer to those of its five sister exchanges, The Nasdaq Stock Market LLC; Nasdaq BX, Inc.; Nasdaq PHLX LLC; Nasdaq ISE, LLC; and Nasdaq MRX, LLC (“Affiliated Exchanges”). The shell structure currently contains eight (8) Chapters which, once complete, will apply a common set of rules to the Affiliated Exchanges. See Securities Exchange Act Release No. 82171 (November 29, 2017), 82 FR 57516 (December 5, 2017) (SR–GEMX–2017–54).
subject to the FINRA Code of Arbitration Procedure.

Because the Affiliated Exchanges are also parties to similar Regulatory Contracts with FINRA that make their members and associated persons of such members subject to the FINRA Code of Arbitration Procedure, the Exchange believes it is pertinent that a common set of rules on arbitration be included in the General section of the Rulebook’s shell. Nasdaq completed this process recently \(^5\) and, pursuant to subsequent filings, the intention is to replace the existing arbitration rules for each of the Affiliated Exchanges by incorporating the Nasdaq rules on arbitration by reference. Therefore, the Exchange will incorporate by reference the Proposed Arbitration Rules in “General 6 Arbitration” of the shell’s “General Rules” section.

The relocation and harmonization of the arbitration rules is part of the Exchange’s continued effort to promote efficiency and conformity of its processes with those of its Affiliated Exchanges. \(^6\) The Exchange believes that the adoption and placement of the Proposed Arbitration Rules to their new location in the shell will facilitate the use of the Rulebook by Members of the Exchange who are members of other Affiliated Exchanges. Moreover, the proposed changes are of a conforming nature and will not amend the substance of the adopted rules other than to update the language to that of the Proposed Arbitration Rules, and to make conforming cross-reference changes.

GEMX will continue to file proposed rule changes to amend its General 6 Rules until such time as it receives an exemption from the Securities and Exchange Commission, pursuant to its authority under Section 36 of the Exchange Act of 1934 (“Act”) and Rule 0–12 \(^7\) thereunder, from the Section 19(b) filing requirements to separately file a proposed rule change to amend General 6.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act, \(^8\) in general, and furthers the objectives of Section 6(b)(5) of the Act, \(^9\) in particular, that in it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by promoting efficiency and structural conformity of the Exchange’s processes with those of the Affiliated Exchanges and to make the Exchange’s Rulebook easier to read and more accessible to its Members. The Exchange believes that the adoption and harmonization of the arbitration rules and cross-reference updates are of a non-substantive nature.

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 not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes do not impose a burden on competition because, as previously stated, they are (i) of a non-substantive nature, (ii) intended to harmonize the structure of the Exchange’s rules with those of its Affiliated Exchanges, and (iii) intended to organize the Rulebook in a way that it will ease the Members’ navigation and reading of the rules across the Affiliated Exchanges.

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

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)(iii) of the Act \(^10\) and subparagraph (f)(6) of Rule 19b–4 thereunder. \(^11\) 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);
• Send an email to rule-comments@sec.gov. Please include File Number SR–GEMX–2018–35 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–GEMX–2018–35. 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 website (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 website 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 the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

---


\(^6\) See footnote 3.


\(^8\) 15 U.S.C. 78b(b).


\(^11\) 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file 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. The Exchange has satisfied this requirement.
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. ICC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICC proposes revising its Stress Testing Framework and its Liquidity Risk Management Framework. Specifically, ICC proposes clarifying changes regarding current aspects of its stress testing and liquidity stress testing practices to address comments received from independent validations, as well as additional clean-up changes. The independent validator comments revolve around clarification updates that do not change ICC’s current stress testing and liquidity stress testing practices. ICC’s proposed changes to address the independent validator comments include updates to correct inconsistencies between section numbering and the table of contents, ensure that scenarios are categorized consistently across the ICC Stress Testing Framework and the ICC Liquidity Risk Management Framework, define potentially unclear terminology, and clarify or include additional detail relating to potentially ambiguous phrases or text such that ICC’s documentation provides a clearer view of its stress testing and liquidity stress testing practices. ICC believes such revisions will facilitate the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions for which it is responsible. The proposed revisions are described in detail as follows.

Stress Testing Framework

ICC proposes revisions to the Stress Testing Framework to address independent validator comments and to make clarification and clean-up changes to enhance readability. ICC proposes clean-up changes to the Table of Contents to add two sections, which are not new to the document, but were previously excluded from the Table of Contents. ICC also proposes, for clarity, updates to the ‘Overview’ section to abbreviate “Risk Committee” to “RC.” ICC proposes corresponding changes throughout the document.

ICC proposes amendments to the ‘Predefined Scenarios’ section of the Stress Testing Framework. ICC proposes to divide the predefined scenarios into four categories. Previously, the Stress Testing Framework divided the predefined scenarios into three categories by combining the Historically Observed Extreme but Plausible Market Scenarios: Severity of Losses in Response to a Baseline Credit Event and the Hypothetically Constructed (Forward Looking) Extreme but Plausible Market Scenarios into one category. ICC proposes to separate these scenarios into two categories to maintain uniformity throughout the Stress Testing Framework since each represents a distinct sub-section in the ‘Predefined Scenarios’ section of the Stress Testing Framework. Additionally, ICC proposes to categorize the Discordant Spread Scenarios (i.e., scenarios designed to reproduce significant discordant outcomes during the considered period) and the Opposite Discordant Spread Scenarios (i.e., scenarios constructed using the opposite discordant outcomes to those observed during the considered period) as Historically Observed Extreme but Plausible in the Liquidity Risk Management Framework, which include the Discordant Spread Scenarios and the Opposite Discordant Spread Scenarios.

ICC proposes clarifying changes to the ‘Display of Discordant Behavior among Instrument Groups’ section. ICC proposes to more clearly define discordant change as discordant relative spread move. ICC proposes to add clarifying language to define the market depth of sovereign reference entities in terms of the observed weekly trading volumes from the Depository Trust & Clearing Corporation (“DTCC”). In addition, ICC proposes to include language to clarify that the historical period selected to represent the greatest combined discordant change for sovereign reference entities can be different from the one selected for corporate single names (“SNs”). ICC proposes enhancements to the ‘Reverse Stress Testing: Guaranty Fund Adequacy Analysis’ section to provide additional clarity regarding how ICC performs such analysis. Specifically, ICC proposes to add explanatory language to note that, upon the simultaneous default of two Clearing Participant (“CP”) affiliate groups (“AGs”), ICC considers additional adverse spread realizations and idiosyncratic credit events associated with reference obligations on which the stress tested CP sold protection. ICC proposes enhancements to the ‘Interest Rate Sensitivity Analysis’

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to ICC’s Stress Testing Framework and ICC’s Liquidity Risk Management Framework

October 15, 2018.

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 October 1, 2018, ICE Clear Credit LLC (“ICC”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change described in Items I, II, and III below, which Items have been prepared primarily by ICC. ICC filed the proposed rule changes pursuant to Section 19(b)(3)(A) of the Act,3 and Rule 19b–4(f)(4)(ii) thereunder,4 so that the proposal was immediately effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The principal purpose of the proposed rule change is to revise the ICC Stress Testing Framework and the ICC Liquidity Risk Management Framework. These revisions do not require any changes to the ICC Clearing Rules (“Rules”).

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed

section to further clarify its analysis. To avoid confusing interest rate shocks as haircuts, ICC proposes to clarify that interest rate shocks used for stress testing are based on interest rate shocks observed during historical periods used to estimate haircuts.

ICC proposes clarification changes to the ‘Guaranty Fund Sizing Sensitivity’ section. ICC’s Guaranty Fund (“GF”) model aims to establish financial resources that are sufficient to cover hypothetical losses associated with the simultaneous credit events where up to five SN Risk Factor Groups (“RFGs”) are impacted. In that, two of the selected SN RFGs are CP AGs (i.e., Cover-2 GF sizing) and the other three RFGs are non-CP RFGs. Under the alternative combination, three of the selected SN RFGs are CP AGs (i.e., Cover-3 GF sizing) and the other two RFGs are non-CP RFGs. Given that two or three of the selected SN RFGs are CP AGs, ICC proposes to provide specific reference to CP AGs when referring to Cover-2 and Cover-3 GF sizing. ICC proposes corresponding changes throughout the document when referencing Cover-2 and Cover-3.

ICC proposes updates to the ‘Interpretation of Results’ section. For clarity, ICC proposes revisions to specify when it assesses Cover-2 in terms of two CP AGs generating the largest uncollateralized stress losses (i.e., stress losses over their corresponding financial resources) versus two CP AGs generating the largest consumption of the GF. ICC proposes incorporating the Discordant Spread Scenarios and the Opposite Discordant Spread Scenarios in its list of Historically Observed and Hypothetically Constructed Extreme but Plausible Scenarios to ensure consistency with the Historically Observed Extreme but Plausible Scenarios set forth in the Liquidity Risk Management Framework, which include the Discordant Spread Scenarios and the Opposite Discordant Spread Scenarios. In addition, ICC proposes to further clarify the role of large position requirements, noting that large position requirements, although initially excluded, are included in the available total margin used to cover hypothetical losses from stress test results.

ICC proposes amending the ‘Post-Stress Testing Review & Governance Structure’ section to more clearly reflect the ICC Risk Department’s reporting and stress testing obligations. The proposed changes clarify that, for each considered security-based swap transactions in ICC’s custody or control, or for which ICC is responsible. The proposed changes to the Stress Testing Framework and the Liquidity Risk Management Framework to address independent validator comments provide additional clarity and transparency regarding ICC’s stress testing and liquidity stress testing practices and enhance ICC’s approach to identifying potential weaknesses in the risk methodology as well as the methodology for testing the sufficiency of ICC’s liquidity resources. The clarification and clean-up changes that enhance readability further ensure that the documentation of ICC’s Stress Testing Framework and Liquidity Risk Management Framework remains up-to-date, clear, and transparent. ICC believes that having policies and procedures that clearly and accurately document ICC’s stress testing and liquidity stress testing practices are an important component to the effectiveness of ICC’s risk management system, which promotes the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions and contributes to the safeguarding of securities and funds associated with security-based swap transactions in ICC’s custody or control, or for which ICC is responsible. As such, the proposed rule changes are designed to promote the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions and to contribute to the safeguarding of securities and funds associated with security-based swap transactions in ICC’s custody or control, or for which ICC is responsible within the meaning of Section 17A(b)(3)(F) of the Act.8

In addition, the proposed revisions to the Stress Testing Framework and the Liquidity Risk Management Framework are consistent with the relevant requirements of Rule 17Ad–22.9 Rule 17Ad–22(b)(3)10 requires ICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain sufficient financial resources to withstand, at a minimum, a default by the two CP families to which it has the largest exposures in extreme but plausible market conditions. The proposed changes to the Stress Testing Framework and the Liquidity Risk Management Framework provide further clarity and transparency regarding ICC’s

---

5 ICC deems each SN reference entity a Risk Factor. ICC deems a set of SN Risk Factors related by a common parental ownership structure a RFG.


7 Id.

8 Id.


10 17 CFR 240.17Ad–22(b)(3).
stress testing and liquidity stress testing practices and enhance ICC’s approach to identifying potential weaknesses in the risk methodology as well as the methodology for testing the sufficiency of ICC’s liquidity resources, thereby ensuring that ICC maintains sufficient financial resources to withstand, at a minimum, a default by the two CP families to which it has the largest exposures in extreme but plausible market conditions, consistent with the requirements of Rule 17Ad–22(b)(3).11

Rule 17Ad–22(d)(8)12 requires ICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to have governance arrangements that are clear and transparent to fulfill the public interest requirements in Section 17A of the Act.13 By updating the Stress Testing Framework and the Liquidity Risk Management Framework so that the documents more clearly reflect the assignment of responsibilities to the ICC Risk Department in terms of reporting and stress testing obligations, the proposed changes will ensure that ICC’s governance of the Stress Testing Framework and the Liquidity Risk Management Framework is clear, transparent, and documented accurately, consistent with the requirements of Rule 17Ad–22(d)(8).14

(B) Clearing Agency’s Statement on Burden on Competition

ICC does not believe the proposed rule changes would have any impact, or impose any burden, on competition. The proposed changes to ICC’s Stress Testing Framework and ICC’s Liquidity Risk Management Framework will apply uniformly across all market participants. Therefore, ICC does not believe the proposed rule changes impose any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency’s Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

III. Date of Effectiveness of the Proposed Rule Change

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)

of the Act and paragraph (f) of Rule 19b–4 thereunder. 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.

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– ICC–2018–010 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. All submissions should refer to File Number SR–ICC–2018–010. 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 website (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 website 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 filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit’s website at https:// www.theice.com/clear-credit/regulation.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICC–2018–010 and should be submitted on or before November 9, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.15

Eduardo A. Aleman, Assistant Secretary.

[FR Doc. 2018–22776 Filed 10–18–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Clearing Agency Policy on Capital Requirements and the Clearing Agency Capital Replenishment Plan

October 15, 2018.

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 October 4, 2018, The Depository Trust Company (“DTC”) 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 clearing agency. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act3 and Rule 19b–4(f)(4) thereunder.4 The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to (i) the Clearing Agency Policy on Capital Requirements (“Capital Policy” or “Policy”) of DTC and its affiliates, National Securities Clearing Corporation (“NSCC”) and Fixed Income Clearing Corporation (“FICC,” and together with DTC and NSCC, the “Clearing Agencies”); and (ii) the Clearing Agency Capital Replenishment Plan (“Capital Replenishment Plan” or “Plan”) of the


Clearing Agencies. In particular, the proposed revisions to the Capital Policy and Capital Replenishment Plan would (1) correct typographical errors and make other technical revisions to correct and simplify statements in the Policy and Plan; (2) replace references in the Policy and Plan to the “Credit Risk Capital Requirement” with the “Corporate Contribution;” and (3) update references in the Policy to the Recovery & Wind-down Plans of each of the Clearing Agencies, which were recently adopted by the Clearing Agencies, as described in greater detail below.

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Clearing Agencies are proposing to revise the Capital Policy and Capital Replenishment Plan, which were adopted by the Clearing Agencies in July 2017 and are maintained by the Clearing Agencies in compliance with Rule 17Ad–22(e)(15) under the Act.6

Overview of the Capital Policy and Capital Replenishment Plan

The Capital Policy sets forth the manner in which each Clearing Agency identifies, monitors, and manages its general business risk with respect to the requirement to hold sufficient liquid net assets (“LNA”) funded by equity to cover potential general business losses so the Clearing Agency can continue operations and services as a going concern if such losses materialize.7 The amount of LNA funded by equity to be held by each of the Clearing Agencies for this purpose is defined in the Policy as the General Business Risk Capital Requirement. The Policy provides that the General Business Risk Requirement is calculated for each Clearing Agency as the greatest of three separate calculations—(1) an amount based on that Clearing Agency’s general business risk profile (“Risk-Based Capital Requirement”), (2) an amount based on the time estimated to execute a recovery or orderly wind-down of the critical operations of that Clearing Agency (“Recovery/Wind-down Capital Requirement”), and (3) an amount based on an analysis of that Clearing Agency’s estimated operating expenses for a six month period (“Operating Expense Capital Requirement”). On an annual basis, each of these three capital requirements are measured, and the General Business Risk Capital Requirement for each Clearing Agency are determined as the greatest of these calculations.

Currently, the Capital Policy also addresses how each Clearing Agency maintains a portion of retained earnings as LNA funded by equity as its Credit Risk Capital Requirement, as a part of its management of credit risk and pursuant to their respective rules.8 These resources are maintained to address losses due to a participant default, and are held in addition to the LNA funded by equity held by each of the Clearing Agencies as its General Business Risk Capital Requirement. The Capital Policy describes how each Clearing Agency’s General Business Risk Capital Requirement and Credit Risk Capital Requirement fit within the Clearing Agencies’ Capital Framework, where the Total Capital Requirement of each Clearing Agency is calculated as the sum of its General Business Risk Capital Requirement and Credit Risk Capital Requirement.

The Policy also provides a plan for the replenishment of capital through the Capital Replenishment Plan. The Capital Replenishment Plan was adopted by the Clearing Agencies as a plan for the replenishment of capital by each Clearing Agency should its equity fall close to or below the amount held as its Total Capital Requirement pursuant to the Capital Policy. The Capital Replenishment Plan identifies the circumstances that would trigger implementation of the Plan; the roles, responsibilities, and guiding principles for implementation of the Plan; and an overview and description of each of the tools that may be used to replenish capital.

Proposed Revisions to the Capital Policy and Capital Replenishment Plan

As described in greater detail below, the Clearing Agencies are proposing to make certain revisions to the Capital Policy and Capital Replenishment Plan.

First, the proposed revisions would correct typographical errors and make other technical revisions to correct and simplify statements in the Capital Policy and Capital Replenishment Plan. Second, the proposed revisions would replace references to the “Credit Risk Capital Requirement” with “Corporate Contribution.” This proposed change would reflect the implementation of recent revisions to the Clearing Agencies’ Rules regarding allocation of losses.10 Finally, the proposed revisions would update the description of the calculation of the Recovery/Wind-down Capital Requirement in the Capital Policy to clarify that the Recovery & Wind-down Plans of each of the Clearing Agencies have been adopted by the Clearing Agencies.11

These proposed revisions are designed to enhance the clarity of the Policy and Plan and help ensure that they continue to operate as intended.

1. Technical Revisions

DTC is proposing technical revisions to the descriptions within the Capital Policy and Capital Replenishment Plan that would correct typographical errors, including, for example, removing a phrase that was incorrectly repeated in the same sentence. These revisions would also correct an error in Section 3 of the Policy, where the document was incorrectly referred to as the Plan.

Such revisions would also update the documents. For example, the proposed changes would replace references in the Capital Policy and Capital Replenishment Plan to the Finance/Capital Committee of the Boards, which was disbanded September 2017, with

---

6 17 CFR 240.17Ad–22(e)(15).
9 LNA funded by equity held as the Clearing Agencies’ Credit Risk Capital Requirement is held in addition to resources held by the Clearing Agencies for credit risk in compliance with Rule 17Ad–22(e)(4) under the Act and in addition to resources held by the Clearing Agencies for liquidity risk in compliance with Rule 17Ad–22(e)(7). 17 CFR 240.17Ad–22(e)(4), (7).
the Boards, which has taken on the responsibilities of this Committee set forth in the Policy and Plan. These revisions would also include updating the Capital Replenishment Plan to revise the name of the “Capital Contributions to DTCC Subsidiaries and Joint Ventures Policy” to the new name of this document, the “Capital Contributions Policy.” 12

Finally, the proposed revisions would also simplify the descriptions in these documents. For example, these revisions would add a defined term for the Clearing Agencies’ Rules to the Policy in order to simplify references to such rules and procedures in this document.

2. Addition of Corporate Contribution

The proposed revisions would also replace references in the Capital Policy and Capital Replenishment Plan to the “Credit Risk Capital Requirement” with the “Corporate Contribution.”

Currently, the Capital Policy describes how each Clearing Agency maintains a portion of retained earnings as LNA funded by equity as its Credit Risk Capital Requirement, in accordance with their respective Rules. Recently, the Clearing Agencies implemented revisions to their respective Rules to enhance the process by which they may allocate losses to their participants if the size of the losses exceed their prefunded resources.13 Such revisions included an amendment to the calculation and application of the amount of LNA funded by equity that are currently referred to in the Capital Policy and Capital Replenishment Plan as the Credit Risk Capital Requirement.

Specifically, the DTC Rules previously required that DTC could, in its discretion and in such amounts as it would determine, charge its existing retained earnings and undivided profits to a loss or liability, to the extent that it is not satisfied by the Actual Participants Fund Deposit and Preferred Stock of the defaulting Participant. Pursuant to these recent changes, the DTC Rules now require that DTC contribute an amount equal to 50 percent of DTC’s General Business Risk Capital Requirement (as such amount is defined in the Capital Policy) (“Corporate Contribution”) towards losses or liabilities arising from a Participant default or non-default event. DTC may also voluntarily apply amounts greater than the Corporate Contribution, as the DTC Board of Directors may determine. The Corporate Contribution applied to any losses arising from events that may occur during the next 250 business days would be reduced to the remaining unused portion of Corporate Contribution, if any.14

The amendments to the calculation and application of the resources that are now referred to as the Corporate Contribution did not change how these resources are described within the Policy or the Plan. The Corporate Contribution continues to represent resources maintained by the Clearing Agencies to address losses due to a participant default, as a part of their management of credit risk.15 These resources also are still held in addition to the LNA funded by equity held by each of the Clearing Agencies as its General Business Risk Capital Requirement.

Therefore, the Capital Policy and Capital Replenishment Plan would be revised to replace references to the Credit Risk Capital Requirement with references to the Corporate Contribution, and no other changes are needed to the description of this amount.

3. Update References to the Recovery & Wind-Down Plans of the Clearing Agencies

The proposed revisions would also update the Capital Policy to make clear that the Recovery & Wind-down Plans of the Clearing Agencies have been adopted by the Clearing Agencies.16 Such references are currently made in connection with the description of the calculation of the Recovery/Wind-down Capital Requirement.

The Recovery/Wind-down Capital Requirement is an amount based on the time estimated to execute a recovery or orderly wind-down of the critical operations of that Clearing Agency and is used by the Clearing Agencies to determine their General Business Risk Capital Requirement. Each of the Clearing Agencies recently adopted a Recovery & Wind-Down Plan, which provide plans for the recovery and orderly wind-down of each of the Clearing Agencies necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses.17 The Recovery & Wind-down Plans each include an analysis of the calculation of the Recovery/Wind-down Capital Requirement, based on the formula that is set forth in the Capital Policy.

The Clearing Agencies are proposing to revise the Capital Policy to make clear that the Recovery & Wind-down Plans have now been adopted by the Clearing Agencies.

2. Statutory Basis

The Clearing Agencies believe that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, the Clearing Agencies believe that the Capital Policy and the Capital Replenishment Plan are both consistent with Section 17A(b)(3)(F) of the Act 18 and Rule 17Ad–22(e)(15) under the Act,19 for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of the Clearing Agencies be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of the Clearing Agency or for which it is responsible.20 Together, the Capital Policy and the Capital Replenishment Plan are designed to ensure that each of the Clearing Agencies hold sufficient LNA funded by equity to cover potential general business losses so that it can continue the prompt and accurate clearance and settlement of securities transactions and can continue to assure the safeguarding of securities and funds which are in its custody or control or for which it is responsible if those losses materialize. By correcting errors and updating the Capital Policy and Capital Replenishment Plan to be consistent with recent changes implemented by the Clearing Agencies, the proposed revisions would allow the Clearing Agencies to maintain these documents to operate in the way they were intended. Therefore, such proposed revisions would be consistent with the requirements of Section 17A(b)(3)(F) of the Act.21

Rule 17Ad–22(e)(15) requires the Clearing Agencies to establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor, and manage their respective general business risk and hold sufficient

12 This document is an internal policy that governs how The Depository Trust & Clearing Corporation may invest capital in its subsidiaries, including the Clearing Agencies, as well as affiliated joint ventures and non-affiliated companies.

13 Supra note 10.

14 See supra notes 9 and 10.

15 As noted above, unlike the resources referred to in the Policy and Plan as the Credit Risk Capital Requirement, the Corporate Contribution would also be available to the Clearing Agencies to address losses due to events other than a participant default.

16 Supra note 11.

17 Id.


19 17 CFR 240.17Ad–22(e)(15).


21 Id.
liquid net assets funded by equity to cover potential general business losses so that the Clearing Agencies can continue operations and services as a going concern if those losses materialize.\(^\text{22}\) As originally implemented, the Capital Policy and the Capital Replenishment Plan were designed to meet the requirements of Rule 17Ad–22(e)(15) under the Act.\(^\text{23}\)

As stated above, the proposed revisions would update the Capital Policy and Capital Replenishment Plan to be consistent with recent changes implemented by the Clearing Agencies. In this way, the proposed changes would allow the Clearing Agencies to maintain these documents in a way that to meet these requirements. Therefore, such proposed revisions would be consistent with the requirements of Rule 17Ad–22(e)(15) under the Act.\(^\text{24}\)

(B) Clearing Agency’s Statement on Burden on Competition

Each of the Clearing Agencies believes that none of the proposed revisions to the Capital Policy and the Capital Replenishment Plan would have any impact, or impose any burden, on competition. The Policy and the Plan are maintained by the Clearing Agencies in order to satisfy their regulatory requirements and generally reflect internal tools and procedures. Tools and procedures that have a direct impact on the rights, responsibilities or obligations of members or participants of the Clearing Agencies are reflected in the Clearing Agencies’ Rules. Accordingly, the Capital Policy and Capital Replenishment Plan themselves are documents that enhance the Clearing Agencies’ regulatory compliance and internal management and do not have any impact, or impose any burden, on competition.

The proposed revisions to correct and update the Capital Policy and Capital Replenishment Plan would not affect any changes on the fundamental purpose or operation of these documents and, as such, would also not have any impact, or impose any burden, on competition.

(C) Clearing Agency’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Clearing Agencies have not solicited or received any written comments relating to this proposal. The Clearing Agencies will notify the Commission of any written comments received by the Clearing Agencies.

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) of the Act\(^\text{25}\) and paragraph (f) of Rule 19b–4 thereunder.\(^\text{26}\) 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.

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–DTC–2018–008 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–DTC–2018–008 and should be submitted on or before November 9, 2018. For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.\(^\text{27}\)

Edward A. Aleman,
Assistant Secretary.

[PR Doc. 2018–22779 Filed 10–18–18; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15746 and #15747; NORTH CAROLINA Disaster Number NC–00100]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of North Carolina

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of North Carolina (FEMA–4393–DR), dated 10/12/2018.


DATES: Issued on 10/12/2018.

Physical Loan Application Deadline Date: 12/11/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 07/12/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.


SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President’s major disaster declaration on 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 DTC and on DTC’s website (http://dtcc.com/legal/sec-rule-filings.aspx). All comments received will be posted without change. Persons submitting comments are cautioned that we do not reedit or recharacterize identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–DTC–2018–008 and should be submitted on or before November 9, 2018.

\(^{22}\) 17 CFR 240.17Ad–22(e)(15).

\(^{23}\) See supra note 5.

\(^{24}\) 17 CFR 240.17Ad–22(e)(15).


10/12/2018, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

**Primary Counties:** Alleghany, Anson, Ashe, Beaufort, Bladen, Brunswick, Cabarrus, Carteret, Chatham, Columbus, Craven, Cumberland, Dare, Duplin, Granville, Greene, Harnett, Hoke, Hyde, Johnston, Jones, Lee, Lenoir, Montgomery, Moore, New Hanover, Onslow, Pamlico, Pender, Person, Randolph, Richmond, Robeson, Sampson, Scotland, Stanly, Union, Wayne, Wilson, Yancey.

The number assigned to this disaster for physical damage is 157468 and for economic injury is 157470.

(Catalog of Federal Domestic Assistance Number 59008)

Jsmaes Rivera,
Associate Administrator for Disaster Assistance.

[FR Doc. 2018–22867 Filed 10–18–18; 8:45 am]

BILLING CODE 8025–01–P

**SMALL BUSINESS ADMINISTRATION**

[Disaster Declaration #15742 and #15743; FLORIDA Disaster Number FL–00140]

**Presidential Declaration of a Major Disaster for the State of Florida**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a Notice of the Presidential declaration of a major disaster for the State of Florida (FEMA–4399–DR), dated 10/11/2018.

**Incident:** Hurricane Michael.

**Incident Period:** 10/07/2018 and continuing.

**DATES:** Issued on 10/11/2018.

**Physical Loan Application Deadline Date:** 12/10/2018.

**Economic Injury (EIDL) Loan Application Deadline Date:** 07/11/2019.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the President’s major disaster declaration on 10/14/2018, applications for disaster loans may be filed at the address listed above or other locally announced locations. The following areas have been determined to be adversely affected by the disaster:

**Primary Counties (Physical Damage and Economic Injury Loans):** Baker, Decatur, Dougherty, Early, Miller, Seminole.

**Contiguous Counties (Economic Injury Loans Only):** Georgia: Calhoun, Clay, Grady, Lee, Mitchell, Terrell, Worth.

Alabama: Henry, Houston.

Florida: Gadsden, Jackson.

The Interest Rates are:

<table>
<thead>
<tr>
<th>Percent</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.500</td>
<td></td>
</tr>
</tbody>
</table>

The number assigned to this disaster for physical damage is 157448 and for economic injury is 157450.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,
Associate Administrator for Disaster Assistance.

[FR Doc. 2018–22864 Filed 10–18–18; 8:45 am]

BILLING CODE 8025–01–P

**SMALL BUSINESS ADMINISTRATION**

[Disaster Declaration #15744 and #15745; GEORGIA Disaster Number GA–00108]

**Presidential Declaration of a Major Disaster for the State of Georgia**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a Notice of the Presidential declaration of a major disaster for the State of Georgia (FEMA–4400–DR), dated 10/14/2018.

**Incident:** Hurricane Michael.

**Incident Period:** 10/09/2018 and continuing.

**DATES:** Issued on 10/14/2018.

**Physical Loan Application Deadline Date:** 12/13/2018.

**Economic Injury (EIDL) Loan Application Deadline Date:** 07/15/2019.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the President’s major disaster declaration on 10/14/2018, applications for disaster loans may be filed at the address listed above or other locally announced locations. The following areas have been determined to be adversely affected by the disaster:

**Primary Counties:** Calhoun, Clay, Grady, Lee, Mitchell, Terrell, Worth.

The Interest Rates are:

<table>
<thead>
<tr>
<th>Percent</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.500</td>
<td></td>
</tr>
</tbody>
</table>

The number assigned to this disaster for physical damage is 157448 and for economic injury is 157450.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,
Associate Administrator for Disaster Assistance.

[FR Doc. 2018–22864 Filed 10–18–18; 8:45 am]

BILLING CODE 8025–01–P

**SMALL BUSINESS ADMINISTRATION**

[Disaster Declaration #15742 and #15743; FLORIDA Disaster Number FL–00140]

**Presidential Declaration of a Major Disaster for the State of Florida**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a Notice of the Presidential declaration of a major disaster for the State of Florida (FEMA–4399–DR), dated 10/11/2018.

**Incident:** Hurricane Michael.

**Incident Period:** 10/07/2018 and continuing.

**DATES:** Issued on 10/11/2018.

**Physical Loan Application Deadline Date:** 12/10/2018.

**Economic Injury (EIDL) Loan Application Deadline Date:** 07/11/2019.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the President’s major disaster declaration on 10/14/2018, applications for disaster loans may be filed at the address listed above or other locally announced locations. The following areas have been determined to be adversely affected by the disaster:

**Primary Counties (Physical Damage and Economic Injury Loans):** Bay, Franklin, Gulf, Taylor, Wakulla.


The Interest Rates are:

<table>
<thead>
<tr>
<th>Percent</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.000</td>
<td></td>
</tr>
<tr>
<td>2.500</td>
<td></td>
</tr>
<tr>
<td>4.000</td>
<td></td>
</tr>
<tr>
<td>6.000</td>
<td></td>
</tr>
<tr>
<td>7.350</td>
<td></td>
</tr>
<tr>
<td>3.675</td>
<td></td>
</tr>
<tr>
<td>2.500</td>
<td></td>
</tr>
<tr>
<td>2.000</td>
<td></td>
</tr>
<tr>
<td>4.000</td>
<td></td>
</tr>
<tr>
<td>7.350</td>
<td></td>
</tr>
<tr>
<td>3.675</td>
<td></td>
</tr>
<tr>
<td>4.000</td>
<td></td>
</tr>
</tbody>
</table>

The number assigned to this disaster for physical damage is 157448 and for economic injury is 157450.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,
Associate Administrator for Disaster Assistance.

[FR Doc. 2018–22864 Filed 10–18–18; 8:45 am]

BILLING CODE 8025–01–P
For Economic Injury:
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere .......................... 3,675
Non-Profit Organizations without Credit Available Elsewhere .......................... 2,500

The number assigned to this disaster for physical damage is 157428 and for economic injury is 157430.
(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,
Associate Administrator for Disaster Assistance.

[FR Doc. 2018–22846 Filed 10–18–18; 8:45 am]
BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION
[Disaster Declaration #15742 and #15743; Florida Disaster Number FL–00140]

Presidential Declaration Amendment of a Major Disaster for the State of Florida

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Florida (FEMA–4399–DR), dated 10/11/2018.
Incident: Hurricane Michael.
Incident Period: 10/07/2018 and continuing.

DATES: Issued on 10/12/2018.
Physical Loan Application Deadline Date: 12/10/2018.
Economic Injury (EIDL) Loan Application Deadline Date: 07/11/2019.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.


SUPPLEMENTARY INFORMATION: The notice of the President’s major disaster declaration for the State of Florida, dated 10/11/2018, is hereby amended to include the following areas as adversely affected by the disaster:
Primary Counties (Physical Damage and Economic Injury Loans): Calhoun, Gadsden, Jackson, Liberty.
Contiguous Counties (Economic Injury Loans Only):
Florida: Holmes
Alabama: Geneva, Houston.
Georgia: Decatur, Grady, Seminole.

All other information in the original declaration remains unchanged.
(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,
Associate Administrator for Disaster Assistance.

[FR Doc. 2018–22851 Filed 10–18–18; 8:45 am]
BILLING CODE 8025–01–P

DEPARTMENT OF STATE
[Public Notice: 10589]

Department of State Performance Review Board Members

In accordance with section 4314(c)(4) of 5 United States Code, the Department of State has appointed the following individuals to the Department of State Performance Review Board for Senior Executive Service members:
Jeffrey C. Mounts, Chairperson, Deputy Comptroller, Comptroller, Global Financial Services, Department of State;
Maegan Conklin, Assistant Legal Adviser, Office of the Legal Adviser, Department of State;
Eliot Kang, Principal Deputy Assistant Secretary, Bureau of International Security and Nonproliferation, Department of State;
Cathy J. Read, Procurement Executive, Bureau of Administration, Department of State; and
Marc L. Ostfield, Deputy Director, Foreign Service Institute, Department of State.

Dated: September 27, 2018.

William Todd,
Acting, Director General of the Foreign Service and Director of Human Resources, Department of State.

[FR Doc. 2018–22839 Filed 10–18–18; 8:45 am]
BILLING CODE 4710–15–P

DEPARTMENT OF STATE
[Public Notice: 10590]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: “Renaissance Splendor: Catherine de Medici’s Valois Tapestries” Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that the objects to be exhibited in the exhibition “Renaissance Splendor: Catherine de Medici’s Valois Tapestries,” 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 Cleveland Museum of Art, Cleveland, Ohio, from on or about November 18, 2018, until on or about January 21, 2019, 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.


Jennifer Z. Galt, Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–22850 Filed 10–18–18; 8:45 am]
BILLING CODE 4710–05–P


Jennifer Z. Galt, Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–22850 Filed 10–18–18; 8:45 am]
BILLING CODE 4710–05–P

DEPARTMENT OF STATE

Public Notice 10591

Notice of Determinations: Culturally Significant Objects Imported for Exhibition—Determinations: ‘Mrinalini Mukherjee’ Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that the objects to be exhibited in the exhibition “Mrinalini Mukherjee,” 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 at The Met Breuer, New York, New York, from on or about June 4, 2019, until on or about September 29, 2019, 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.


Public Notice of these determinations be published in the Federal Register.


Jennifer Z. Galt, Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–22850 Filed 10–18–18; 8:45 am]
BILLING CODE 4710–05–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in dates.


ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: joyler@srbc.net. Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission’s approval by rule process set forth in 18 CFR 806.22(e) and 806.22(f) for the time period specified above:

Approvals by Rule Issued Under 18 CFR 806.22(f)

1. Repsol Oil & Gas USA, LLC, Pad ID: MURPHY (07 075) D, ABR–201309002.R1; Apolaco Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: September 10, 2018.

2. Repsol Oil & Gas USA, LLC, Pad ID: BUTLER (07 086) J, ABR–201309003.R1; Apolaco Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: September 10, 2018.

3. Repsol Oil & Gas USA, LLC, Pad ID: OLYMPIC LAKE ESTATES (07 083), ABR–201309005.R1; Apolaco Township, Susquehanna County, Pa.; Consumptive Use of Up to 6.0000 mgd; Approval Date: September 10, 2018.

4. SWN Production Company, LLC, Pad ID: Salt Lick Hunting Club-Range-Pad59, ABR–201310002.R1; New Milford Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.9990 mgd; Approval Date: September 10, 2018.

5. SWP LI, Pad ID: Bradford 481, ABR–201309008.R1; Sullivan Township, Tioga County, Pa.; Consumptive Use of Up to 4.0000 mgd; Approval Date: September 21, 2018.

6. Cabot Oil & Gas Corporation, Pad ID: StoddardT P1, ABR–201309012.R1; Lenox Township, Susquehanna County, Pa.; Consumptive Use of Up to 5.0000 mgd; Approval Date: September 24, 2018.


Stephanie L. Richardson, Secretary to the Commission.

[FR Doc. 2018–22765 Filed 10–18–18; 8:45 am]
BILLING CODE 7040–01–P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Recinded for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the approved by rule projects rescinded by the Susquehanna River Basin Commission during the period set forth in dates.


ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110–1788.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436; email: joyler@srbc.net. Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, being rescinded for the consumptive use of water pursuant to the Commission’s approval by rule.
process set forth in 18 CFR 806.22(e) and § 806.22(f) for the time period specified above:

**Rescinded ABR Issued**

1. ARD Operating, LLC, Pad ID: COP Tr 343 Pad B, ABR–201007053.R1; Noyes Township, Clinton County, Pa.; Approval Rescinded: September 13, 2018.

Authority: Public Law 91–575, 84 Stat. 1509 et seq., 18 CFR parts 806, 807, and 808.


Stephanie L. Richardson,
Secretary to the Commission.

---

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**Petition for Exemption; Summary of Petition Received; Anthony Ison, Esq.**

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

**ACTION:** Notice.

**SUMMARY:** This notice is intended to affect the inclusion or omission of information in the FAA's exemption process. Neither awareness of, and participation in, the summary is intended to affect the outcome of the petition process set forth in 18 CFR 806.22(e) and § 806.22(f) for the time period specified above.

**DESCRIPTION OF RELIEF SOUGHT:**

The petition will show that the RPA, which petitioner has operated as PIC, requires the same aeronautical decision-making, concerns for spatial-orientation, and aeronautical operational understanding, as is required in manned aircraft.


Jeff

---

**DEPARTMENT OF TRANSPORTATION**

**Federal Highway Administration**

**Notice of Final Federal Agency Actions on Transportation Project in Washington State**

**AGENCY:** Federal Highway Administration (FHWA), Department of Transportation (DOT).

**ACTION:** Notice of limitation on claims for judicial review of actions by FHWA.

**SUMMARY:** This notice announces actions taken by the FHWA that are final. The action relates to the need to remove wireless communications facilities serving AT&T, Sprint, T-Mobile, and Verizon from the Montlake 76 Service Station and Montlake Boulevard Market property and replace the service provided at a temporary site for the duration of SR 520, I-5 to Medina.

Issued in Washington, DC, on October 12, 2018.

Lirio Liu,
Executive Director, Office of Rulemaking.

**Petition for Exemption**


**Petitioner:** Anthony Ison, Esq. on behalf of Airman Certificate No. 3679272.

**Section(s) of 14 CFR Affected:** 61.159(a), 61.160(f).

**Description of Relief Sought:** Petitioner seeks exemption from §§ 61.159(a) and 61.160(f) for the purpose of obtaining an Airline Transport Pilot (ATP) Certificate with an Airplane Category Rating. More specifically, petitioner seeks to utilize time logged as Pilot-in-Command (PIC) of complex, remotely piloted aircraft (RPA) to satisfy the aeronautical experience prerequisites and requirements, which are set out in the Federal Aviation Regulations (FAR) for obtaining an ATP certificate. As such, this petition will show that petitioner's aeronautical experience and knowledge are equivalent to those requirements set out in the FARs from which the exemption is sought. Furthermore, this petition will show that the RPA, which petitioner has operated as PIC, requires the same aeronautical decision-making, concerns for spatial-orientation, and aeronautical operational understanding, as is required in manned aircraft.

**DATES:** Comments on this petition must be received on or before November 8, 2018.

**ADDRESSES:** Send comments identified by docket number FAA–2018–0612 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 20590–0001, 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 http://www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at http://www.dot.gov/privacy.

Issued in Washington, DC, on October 12, 2018.

Margaret.Kucharski@wsdot.wa.gov.

**SUPPLEMENTARY INFORMATION:** On September 7, 2011, FHWA published a “Notice of Final Federal Agency Actions on Proposed Highway in Washington” in the Federal Register at 76 FR 55459 for the SR 520, I-5 to Medina: Bridge Replacement and HOV Project. Notice is hereby given that, subsequent to the earlier FHWA notice, FHWA has taken final agency actions within the meaning of 23 U.S.C. 139(d)(1) by issuing a NEPA re-evaluation for the SR 520 SR 520, I–5 to Medina: Bridge Replacement and...
HOV Project: Wireless Communications Facility Removal and Relocation (hereafter “re-evaluation”). The action(s) by FHWA and the laws under which such actions were taken, are described in the re-evaluation and the associated agency records. That information is available by contacting FHWA at the addresses provided above. The project proposed to improve safety and mobility for people and goods across Lake Washington by replacing the SR 520 Portage Bay and Evergreen Point bridges and improve existing roadway between Interstate 5 (I–5) in Seattle and Evergreen Point Road in Medina spanning 5.2 miles. The Final Environmental Impact Statement (EIS) for the project was published in January 2011 and the Record of Decision (ROD) was issued in August 2011.

Since issuance of the FHWA ROD, the design and construction approach has been refined such that wireless communications facilities collocated with the Montlake 76 Service Station and Montlake Boulevard Market property would need to be removed to complete construction of the Montlake Phase. A new temporary wireless communications facility will be constructed along Lake Washington Boulevard East near East Miller Street and 26th Avenue East for the duration of SR 520 construction to replace the service provided by the removed facilities. The re-evaluation considering this refinement was issued on September 4, 2018. It identifies and documents potential effects associated with the refinement. This notice only applies to the re-evaluation.

Information about the re-evaluation and associated records are available from FHWA and WSDOT at the addresses provided above and can be found at: https://www.wsdot.wa.gov/Projects/SR520Bridge/Library/15Medina.htm. This notice applies to all Federal agency decisions related to the re-evaluation as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

2. Air: Clean Air Act, as amended [42 U.S.C. 7401–7671(q)].

Issued on: October 9, 2018.
Daniel Mathis, FHWA Division Administrator, Olympia, WA. [FR Doc. 2018–22503 Filed 10–18–18; 8:45 am] BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION
Federal Highway Administration
Notice of Final Federal Agency Actions on Transportation Project in Washington State

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final. The action relates to the need to close and demolish the Montlake Boulevard Market for construction along State Route (SR) 520 in the City of Seattle, King County, State of Washington.

DATES: 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 March 18, 2019. 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: Jeff Horton, Area Engineer, Federal Highway Administration, 711 S Capitol Way, Suite 501, Olympia, WA 98501–1284, 360–753–9411, or jeff.horton@dot.gov; or Margaret Kucharski, Mega Projects Environmental Manager, Washington State Department of Transportation, 999 3rd Ave., Suite 2200, Seattle, WA 98104, 206–770–3500, or Margaret.Kucharski@wsdot.wa.gov.

SUPPLEMENTARY INFORMATION: On September 7, 2011, FHWA published a “Notice of Final Federal Agency Actions on Proposed Highway in Washington” in the Federal Register at 76 FR 55459 for the SR 520, I–5 to Medina: Bridge Replacement and HOV Project. Notice is hereby given that, subsequent to the earlier FHWA notice, FHWA has taken final agency actions within the meaning of 23 U.S.C. 139(l)(1) by issuing a NEPA re-evaluation for the SR 520 SR 520, I–5 to Medina: Bridge Replacement and HOV Project: Montlake Market Closure and Demolition (hereafter “re-evaluation”). The action(s) by FHWA and the laws under which such actions were taken, are described in the re-evaluation and the associated agency records. That information is available by contacting FHWA at the addresses provided above.

The project proposed to improve safety and mobility for people and goods across Lake Washington by replacing the SR 520 Portage Bay and Evergreen Point bridges and improve existing roadway between Interstate 5 (I–5) in Seattle and Evergreen Point Road in Medina spanning 5.2 miles. The Final Environmental Impact Statement (EIS) for the project was published in January 2011 and the Record of Decision (ROD) was issued in August 2011.

Since issuance of the FHWA ROD, the design and construction approach has been refined such that the Montlake Boulevard Market will need to be closed and demolished as part of construction activities. The re-evaluation considering this refinement was issued on July 18, 2018. It identifies and documents potential effects associated with the refinement. This notice only applies to the re-evaluation. Information about the re-evaluation and associated records are available from FHWA and WSDOT at the
addresses provided above and can be found at: https://www.wsdot.wa.gov/Projects/SR520Bridge/Library/15Medina.htm. This notice applies to all Federal agency decisions related to the re-evaluation as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:


2. Air: Clean Air Act, as amended [42 U.S.C. 7401–7671(q)].


Issued on: October 9, 2018.
Daniel Mathis, FHWA Division Administrator, Olympia, WA.
[FR Doc. 2018–22471 Filed 10–16–18; 8:45 am]
BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION
Federal Motor Carrier Safety Administration
[Docket No. FMCSA–2018–0142]
Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Castignoli Enterprises
AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.
ACTION: Notice of final disposition.
SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its decision to grant Castignoli Enterprises’ (Castignoli) application for a limited 5-year exemption to allow a sleeper berth to be installed in the bed of a Ford F350 pickup truck that, when operated in combination with certain trailers, is a commercial motor vehicle (CMV) under the Federal Motor Carrier Safety Regulations (FMCSRs). A sleeper berth installed in the bed of the pickup truck does not meet the access, location, exit, communication, or occupant restraint requirements for sleeper berths as prescribed in the FMCSRs. The Agency has determined that allowing the sleeper berth to be installed in the bed of the pickup truck would not have an adverse impact on safety and that adherence to the terms and conditions of the exemption will likely achieve a level of safety equivalent to, or greater than, the level of safety provided by the regulation.
DATES: This exemption is applicable October 19, 2018 and ending Thursday, October 19th, 2023.
Docket: For access to the docket to read background documents or comments submitted to notice requesting public comments on the exemption application, go to www.regulations.gov at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The online Federal document management system is available 24 hours each day, 365 days each year. The docket number is listed at the beginning of this notice.
SUPPLEMENTARY INFORMATION:
Background
FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the Federal Register (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the Federal Register (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

Castignoli’s Application for Exemption
Castignoli applied for an exemption from 49 CFR 393.76(a)(3), (b)(2), (c), (d), and (h) to allow a sleeper berth to be installed in the bed of a Ford F350 pickup truck. A copy of the application is included in the docket referenced at the beginning of this notice.

Section 393.76 of the FMCSRs provides various requirements for sleeper berths installed in CMVs. Specific to Castignoli’s exemption application:

1. Section 393.76(a)(3), “Access,” requires a sleeper berth to be constructed so that an occupant’s ready entrance to, and exit from the sleeper berth is not unduly hindered.

2. Section 393.76(b)(2), “Location,” requires a sleeper berth located within the cargo space of a motor vehicle to be securely compartmentalized from the remainder of the cargo space.

3. Section 393.76(c), “Exit from the berth,” requires a direct and ready...
means of exit from a sleeper berth into the driver's seat or compartment.

4. Section 393.76(d).

"Communication with the driver," requires a sleeper berth which is not located within the driver's compartment and has no direct entrance into the driver's compartment to be equipped with a means of communication between the occupant and the driver. The means of communication may consist of a telephone, speaker tube, buzzer, pull cord, or other mechanical or electrical device.

5. Section 393.76(h), "Occupant restraint," requires a motor vehicle manufactured on or after July 1, 1971, and equipped with a sleeper berth to be equipped with a means of preventing ejection of the occupant of the sleeper berth during deceleration of the vehicle. The restraint system must be designed, installed, and maintained to withstand a minimum total force of 6,000 pounds applied toward the front of the vehicle and parallel to the longitudinal axis of the vehicle.

The applicant states that he is the owner/operator of Castignoli, and is the "solo driver of a hot shot hauler, F350 1-ton pickup with trailer . . .". The applicant states that as a solo driver, "there is no ready need for access between the sleeper berth and the driver's compartment." In addition, the applicant states:

I plan to incorporate the sleeper berth into the bed of the tow vehicle. The utilization of this type of sleeper berth, would allow myself (as the sole driver) to meet the hours of [10-hour] service rest period requirements by utilizing a sleeper berth incorporated into the bed of the vehicle (Rear covered, ventilated, insulated, bed with cap and full size twin mattress) in lieu of a motel each evening. The tow vehicle/trailer combination would be operating on the roadway during my 10-hour rest period, so there is no benefit in having the access requirements to the driver compartment, nor any need for communication with the driver (myself), nor any occupant restraint requirement as the vehicle is not moving while I am sleeping. The sleeper berth is separate from the trailer behind the tow vehicle, and is therefore separate from the cargo.

The current FMCSR regulatory requirements for sleeper berth access seem to rely on the assumption that one driver is driving while another driver is in the sleeper berth, and that the truck is moving always. The situation that I have as a single driver is that when I am off duty, the vehicle is not moving and therefore direct access to the sleeper berth area should not be required, and since the vehicle is not moving there is no need for occupant restraint systems nor a means for communication with the driver. All other dimensional requirements, ventilation, and protection against exhaust and fuel leaks will be met.

The applicant states that because of mobility issues associated with a partially fused spine, it is easier for him to access a sleeper berth installed in the bed of the pickup truck as opposed to a sleeper berth that could be installed in the back seat of the pickup truck that meets the requirements of the FMCSRs. The exemption would apply only to Castignoli's sole driver and pickup truck. Castignoli believes that the sleeper berth installed in the bed of the pickup truck will maintain a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

Comments

FMCSA published a notice of the application in the Federal Register on April 24, 2018, and asked for public comment (83 FR 17883). The Agency received sixty-five comments, all from individuals. Nearly all of the commenters (61) supported the exemption application. These commenters stated that sleeper berth requirements should be flexible enough to allow a sleeper berth to be accessed from outside the driver compartment for solo operators, and without the regulatory requirements pertaining to access, exit from the berth, communication with the driver, and occupant restraint for vehicles that are not moving during the sleeper berth rest period. Two commenters opposed the exemption application, expressing concerns that a sleeper berth installed in the bed of a pickup truck will not be large enough to allow the driver enough space to get adequate rest. Two commenters did not express support or oppose the exemption application.

FMCSA Decision

The FMCSA has evaluated the Castignoli exemption application, and the comments received. The Agency believes that granting the temporary exemption to allow a sleeper berth to be installed in the pickup truck bed will provide a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption. Sleeper berths provide an option for drivers to obtain the rest necessary under the hours-of-service rules in part 395 of the FMCSRs without having to pay lodging costs at a hotel/motel. In the case of team driving operations, a sleeper berth allows one person to obtain the necessary rest (a "relief driver") while the other person is driving, allowing a vehicle to be operated continuously and thereby increasing productivity.

Previous rulemakings have specifically noted the use of sleeper berths by relief drivers in team driving operations. The sleeper berth requirements were revised in April 1974 to increase the minimum interior dimensional requirements for sleeper berths in CMVs (39 FR 14710). In that final rule, the Federal Highway Administration's Bureau of Motor Carrier Safety (the predecessor to FMCSA) stated that "In sleeper berth trucking operations it is of critical importance that relief drivers be fresh and alert when they assume their driving tasks." [Emphasis added.] Additionally, when considering possible changes to the shape of the sleeper berth, the Bureau of Motor Carrier Safety stated that use of "slant-back" cab designs which incorporate a slanted rear cab wall and do not provide a rectangular sleeper berth compartment was not permissible because it "represents an intrusion into the relief driver's sleeping space." [Emphasis added.]

In team driving operations, it is important for the person in the sleeper berth (i.e., the relief driver) to be able to communicate with the person driving the vehicle, to be able to directly access the driver's seat or compartment, and to be restrained when the vehicle is in motion. These provisions are not applicable, however, in the case of Castignoli where a solo driver is operating a pickup truck and a trailer, and the sleeper berth is only used by the solo driver when the vehicle is not in motion. In this operating scenario, FMCSA believes that as long as the sleeper berth dimensional ($393.76(a)(1)) shape (§393.76(a)(2)), equipment (§393.76(e)), ventilation (§393.76(f)), and protection against exhaust and fuel leaks and exhaust heat (§393.76(g)) provisions are satisfied, the solo driver will be able to obtain the necessary rest and there will be no degradation in safety. Additionally, the Agency believes that allowing flexibility in the location of the sleeper berth is likely to improve the overall level of safety to the motoring public by allowing drivers additional options to get their mandatory rest periods.

Terms and Conditions for the Exemption

The Agency hereby grants the exemption for a 5-year period, beginning October 19, 2018 and ending
Thursday, October 19, 2023. During the temporary exemption period, Castignoli will be allowed to utilize a sleeper berth installed in the bed of a pickup truck that, when operated in combination with certain trailers, is a CMV. The sleeper berth must comply fully with the requirements of §393.76(a)(1), §393.76(a)(2), §393.76(e), §393.76(f), and §393.76(g). The sleeper berth shall be used only by the owner/operator of Castignoli, and no other person is permitted to be in the sleeper berth while the vehicle is in motion.

The exemption will be valid for 5 years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) Castignoli fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31135(b).

Interested parties possessing information that would demonstrate that Castignoli’s use of a sleeper berth installed in the bed of pickup truck when operating as a CMV is not achieving the requisite statutory level of safety should immediately notify FMCSA. The Agency will evaluate any such information and, if safety is being compromised or if the continuation of the exemption is not consistent with 49 U.S.C. 31136(e) and 31135(b), will take immediate steps to revoke the exemption.

Preemption

In accordance with 49 U.S.C. 31136(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to Castignoli Enterprises operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

Issued on: October 10, 2018.
Raymond P. Martinez,
Administrator.

DEPARTMENT OF TRANSPORTATION
Federal Motor Carrier Safety Administration
[ docket No. FMCSA-2015-0480]
Commercial Driver’s License Standards: Application for Exemption; CRST Expedited

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.
ACTION: Notice of final disposition; grant of application for exemption.

SUMMARY: FMCSA announces its decision to renew CRST Expedited (CRST) exemption from the regulation that requires a commercial learner’s permit (CLP) holder to be accompanied by a commercial driver’s license (CDL) holder with the proper CDL class and endorsements, seated in the front seat of the vehicle while the CLP holder performs behind-the-wheel training on public roads or highways. Under the terms and conditions of this exemption, a CLP holder who has documentation of passing the CDL skills test may drive a commercial motor vehicle (CMV) for CRST without being accompanied by a CDL holder in the front seat of the vehicle. The exemption enables CLP holders to drive as part of a team with the same regulatory flexibility as CRST team drivers with CDLs. FMCSA has analyzed the exemption application and the public comments and has determined that the exemption, subject to the terms and conditions imposed, will achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

DATES: This exemption is effective September 24, 2018 and expires September 24, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: (202) 366–4225. Email: MCPSD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:
I. Public Participation

Viewing Comments and Documents
To view comments, as well as documents mentioned in this preamble as being available in the docket, go to www.regulations.gov and insert the docket number, FMCSA–2015–0480, in the “Keyword” box and click “Search.” Next, click the “Open Docket Folder” button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis
FMCSA has authority under 49 U.S.C. 31136(e) and 31135(b) to grant exemptions from certain Federal Motor Carrier Safety Regulations (FMCSRs).

III. Request for Exemption
CRST’s initial exemption application from the provisions of 49 CFR 383.25(a)(1) was submitted in 2015; a copy is in the docket identified at the beginning of this notice. The 2015 application described fully the nature of the CRST’s operations and CMV drivers. The exemption was originally granted on September 23, 2016 (81 FR 65696) for a two-year period. CRST now requests a renewal of the exemption.

The current exemption excuses CRST from the requirement that a driver accompanying a CLP holder must be physically present at all times in the front seat of a CMV, on the condition that the CLP holder has successfully passed an approved CDL skills test. CRST’s 2015 application argued that the existing requirement is inefficient and unproductive, as the company must incur added expense to send the driver...
to his or her home State to collect a CDL document. Under the rule, the driver is not only unable to utilize newly acquired driving skills, but must also forego compensation before obtaining a CDL. CRST believes that FMCSA should renew the exemption for an additional 5-year period because it results in safer drivers. It allows CRST to foster a more productive and efficient training environment by allowing CLP holders to hone their recently acquired driving skills through on-the-job training and to begin earning an income right away, producing immediate benefits for the driver, the carrier, and the economy as a whole.

Method To Ensure an Equivalent or Greater Level of Safety

CRST states that the exemption does not negatively affect safety outcomes. Instead, the exemption allows drivers trained out-of-State to obtain on-the-job experience in CRST’s comprehensive training program while avoiding significant delays and skill degradation. The exemption creates immediate economic and safety benefits for both the CLP holders and CRST—drivers earn an income as part of a team operation while improving their driver skills and gaining valuable experience.

CRST indicated in its renewal application that data show that drivers utilizing the exemption demonstrated better safety outcomes than non-exempt drivers. Through the end of 2017, CRST reported zero accidents to FMCSA involving drivers utilizing the exemption.

In the June 12, 2017, Federal Register, FMCSA granted the renewal of a similar exemption from 49 CFR 383.25(a)(1) to C.R. England, Inc. (C.R. England) for a five-year period. Under the terms and conditions of that exemption, a CLP holder who has documentation of passing the CDL skills test may drive a CMV for C.R. England without being accompanied by a CDL holder in the front seat. The Agency believed that C.R. England’s request for exemption would achieve a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption (82 FR 26975).

Public Comments

On August 9, 2018, FMCSA published notice of this application and requested public comment (83 FR 39495). The Agency received eight comments. Seven individuals posted comments in opposition to renewal of the exemption. For example, Mr. Jarrod Hough wrote, “Why would FMCSA even consider this? The roads and traffic is bad enough already. Permit holders don’t have the experience to operate a commercial vehicle by themselves without the trainer sitting upfront and in the passenger seat. That is what a trainer is for, to teach and give guidance to the student. Not to be in the sleeper berth while the student is left alone.” Mr. Joe Ammons supported the exemption if CRST was required to meet certain conditions, such as showing the exemption was not continued beyond a reasonable period of time before dispatching a permitted driver to his/her home State to complete the licensing process.

FMCSA Response and Decision

FMCSA has evaluated CRST’s application for exemption and the public comments. The Agency believes that CRST’s overall safety performance, as reflected in its “satisfactory” safety rating, will enable it to achieve a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption (49 CFR 381.305(a)). The exemption is restricted to CRST’s CLP holders who have documentation that they have passed the CDL skills test. The exemption will enable these drivers to operate a CMV as a team driver without requiring the accompanying CDL holder be on duty and in the front seat while the vehicle is moving. Because these drivers have already met all the requirements for a CDL, but have yet to pick up the CDL document from their State of domicile, their safety performance is expected to be the same as any other newly-credentialed CDL holder.

Terms and Conditions of the Exemption

Period of the Exemption

This exemption from the requirements of 49 CFR 383.25(a)(1) is effective during the period of September 23, 2018 through September 24, 2023.

Extent of the Exemption

The exemption is contingent upon CRST maintaining USDOT registration, minimum levels of public liability insurance, and not being subject to any “imminent hazard” or other out-of-service (OOS) order issued by FMCSA. Each driver covered by the exemption must maintain a valid driver’s license and CLP with the required endorsements, not be subject to any OOS order or suspension of driving privileges, and meet all physical qualifications required by 49 CFR part 391.

This exemption from 49 CFR 383.25(a)(1) will allow CRST drivers who hold a CLP and have successfully passed a CDL skills test, to drive a CMV without a CDL holder being present in the front seat of the vehicle. The CDL holder must remain in the vehicle at all times while the CLP holder is driving—just not in the front seat.

Preemption

During the period this exemption is in effect, no State may enforce any law or regulation that conflicts with or is inconsistent with the exemption with respect to a person or entity operating under the exemption (49 U.S.C. 31315(d)).

FMCSA Accident Notification

CRST must notify FMCSA within 5 business days of any accidents (as defined by 49 CFR 390.5) involving the operation of any of its CMVs while utilizing this exemption. The notification must be by email to MCPSD@DOT.GOV, and include the following information:

a. Exemption Identifier: “CRST”
b. Date of the accident,
c. City or town, and State, in which the accident occurred, or which is closest to the scene of the accident,
d. Driver’s name and driver’s license number,
e. Vehicle number and State license number,
f. Number of individuals suffering physical injury,
g. Number of fatalities,
h. The police-reported cause of the accident,
i. Whether the driver was cited for violation of any traffic laws, or motor carrier safety regulations,
j. The total driving time and the total on-duty time of the CMV driver at the time of the accident.

Termination

The FMCSA does not believe the CLP-holders covered by the exemption will experience any deterioration of their safety record. However, should this occur, FMCSA will take all steps necessary to protect the public interest, including revocation of the exemption. The FMCSA will immediately revoke the exemption for failure to comply with its terms and conditions.

Issued on: October 12, 2018.
Raymond P. Martinez,
Administrator.
[FR Doc. 2018–22836 Filed 10–18–18; 8:45 am]
DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2006–25290]

Commercial Driver’s License Standards: Application for Exemption; Isuzu North America Corporation (Isuzu)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that it has received an application from Isuzu North America Corporation (Isuzu) requesting an exemption from the Federal requirement to hold a U.S. commercial driver's license (CDL) issued by one of the States. Isuzu requests that the exemption cover 12 of its commercial motor vehicle (CMV) drivers who will test-drive CMVs for Isuzu in the United States. Each of these 12 Isuzu employees holds a valid Japanese commercial license but lacks the U.S. residency necessary to obtain a CDL from one of the States of the United States. Isuzu believes the knowledge and skills tests and training program that drivers undergo to obtain a Japanese commercial license ensures that these drivers will achieve a level of safety that is equivalent to, or greater than, the level of safety that would be obtained by complying with the exemption.

DATES: Comments must be received on or before November 19, 2018.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2006–25290 using any of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the online instructions for submitting comments.
- Mail: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001
- Hand Delivery or Courier: West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- Fax: 1–202–493–2251

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year.

Privacy Act: 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.

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Ms. Pearlie Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4325. Email: MCPSD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2006–25290), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you use your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov and put the docket number, “FMCSA–2006–25290” in the “Keyword” box, and click “Search.” When the new screen appears, click on “Comment Now!” button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the Federal Register (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the Federal Register (49 CFR 381.315(b)) with the reason for the grant or denial, and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption (up to 5 years), and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Request for Exemption

Isuzu has applied for an exemption from the CDL rules, specifically 49 CFR 383.23 that prescribes licensing requirements for drivers operating CMVs in interstate or intrastate commerce. Isuzu requests the exemption because its driver-employees are citizens and residents of Japan, and because they cannot apply for a CDL in any of the United States due to lack of residency. Isuzu explained that the exemption would allow a team of 12 employees (vehicle test engineers, technicians, mechanics and other employees) to drive CMVs in interstate commerce to test and evaluate production and prototype CMVs in the United States in order to design safe and well-tested vehicles for use on U.S. highways. The exemption would further provide an opportunity for these engineers to test how CMVs perform under various environmental and climatic conditions.
The drivers covered by the proposed exemption are Naoto Morimoto, Kenji Sugawara, Ryota Hisamatsu, Takehiro Oshima, Yasuhiro Sakai, Hiroaki Takahashi, Kazunori Aizawa, Atsushi Fujiwara, Kazuya Takahashi, Koichi Ueno, Takahisa Chiba, and Takamasa Ono. According to Isuzu, these drivers will not engage in driving CMVs for purpose of transporting merchandise as a commercial activity.

Each driver holds a valid Japanese commercial license, and as explained by Isuzu in previous exemption requests, drivers applying for a Japanese-issued commercial license must undergo a training program and pass knowledge and skills tests. Isuzu also stated in prior exemption requests that the knowledge and skills tests and training program that Japanese drivers undergo to obtain a Japanese commercial license ensure the exemption provides a level of safety that is equivalent to, or greater than, the level of safety obtained by complying with the U.S. requirement for a CDL. A copy of Isuzu’s application for exemption is available for review in the docket for this notice.

FMCSA has previously determined the process for obtaining a Japanese commercial license is comparable to, or as effective as, the Federal CDL knowledge and skills requirements of 49 CFR part 383 as enforced by the States, and adequately assesses the driver’s ability to operate CMVs in the U.S. Since 2003, FMCSA has granted Isuzu drivers similar exemptions [October 16, 2003 (68 FR 59677); April 3, 2007 (72 FR 15933); April 5, 2007 (72 FR 16870); September 5, 2008 (73 FR 51879); January 5, 2009 (74 FR 334); July 24, 2009 (74 FR 36809)].

Issued on: September 26, 2018.

Larry W. Minor, Associate Administrator for Policy.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8832

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, 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. Currently, the IRS is soliciting comments concerning Form 8832, Entity Classification Election.

DATES: Written comments should be received on or before December 18, 2018 to be considered.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224. Please send separate comments for each specific information collection listed below. You must reference the information collection’s title, form number, reporting or record-keeping requirement number, and OMB number (if any) in your comment.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Charles C. Daniel at (202) 317–5754, at Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at Charles.G.Daniel@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Entity Classification Election. OMB Number: 1545–1516. Form Number: 8832. Abstract: An eligible entity that chooses not to be classified under the default rules or that wishes to change its current classification must file Form 8832 to elect a classification.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Farms.

Estimated Number of Responses: 5,000.

Estimated Time per Response: 7 hours, 10 minutes.

Estimated Total Annual Burden Hours: 35,900.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the 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 collection of information;
(c) whether the collection of information can be made more burdensome by automated collection techniques or other forms of information technology; and
(d) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.


Laurie Brimmer, Senior Tax Analyst.

[FR Doc. 2018–22834 Filed 10–18–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Cemeteries and Memorials, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that a meeting of the Advisory Committee on Cemeteries and Memorials will be held on October 30–October 31, 2018. The meeting sessions will take place at the Denver Regional Benefit Office, 155 Van Gordon Street, Lakewood, CO 80228. Sessions are open to the public, except when the Committee is conducting tours of VA facilities, participating in offsite events, participating in workgroup sessions, and conducting official administrative business. Tours of the VA facilities are closed, to protect Veterans’ privacy and personal information.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on the administration of national cemeteries, soldiers’ lots and plots, the selection of new national cemetery sites, the erection of appropriate memorials, and the adequacy of Federal burial benefits. The Committee will make recommendations to the Secretary regarding such activities.

On the morning of Tuesday, October 30, 2018, the Committee will convene with an open session at the Denver Regional Benefit Office from 8:30 a.m.–11:30 a.m., Mountain Time. The dial-in
number is 1–800–767–1750, access code 02668#. The agenda will include introductions of new members, an overview of Committee activities, and status updates on the 2017 Recommendation for Digital Memorialization. During the afternoon session, from 11:30 a.m. to 4:00 p.m., Mountain Time, the Committee will convene in a closed session to the Public, as it conducts a site visit at the Fort Logan National Cemetery and the student library exhibit at the University of Denver. The exhibit displays stories and artifacts of Veterans interred at Fort Logan National Cemetery.

On the morning of Wednesday, October 31, 2018, the Committee will convene with an open session at the Denver Regional Benefit Office from 8:30 a.m.–10:30 a.m., Mountain Time. The dial-in number is the same. The agenda will include status updates for the National Cemetery Scheduling Office and the Emblems of Belief Regulation; and discussions on any new charges or recommendations. In the afternoon session, 10:30 a.m.–4 p.m., Mountain Time, the Committee convene in a closed session to the Public, as it visits the Pikes Peak National Cemetery to review operations at a new cemetery for the rural Veterans. Under 5 U.S.C. 552b(c) under (9)(B), the meeting is closed because it would reveal information the disclosure of which would, “in the case of an agency, be likely to significantly frustrate implementation of a proposed agency action.” Any precipitous release of those discussions through an open session will frustrate implementation and potentially our Veterans who we consider our greatest customer/benefactor of the commission.

Any member of the public wishing to attend the meeting should contact Ms. Christine Hamilton, Designated Federal Officer, at (202) 461–5681. The Committee will also accept written comments. Comments may be transmitted electronically to the Committee at Christine.hamilton1@va.gov or mailed to the National Cemetery Administration (40A1), 810 Vermont Avenue NW, Room 400, Washington, DC 20420. In the public’s communications with the Committee, the writers must identify themselves and state the organizations, associations, or persons they represent.


Jelessa M. Burney,
Federal Advisory Committee Management Officer.

[FR Doc. 2018–22743 Filed 10–18–18; 8:45 am]
The President

Memorandum of October 16, 2018

Memorandum for the Secretary of Defense [and] the Secretary of Commerce

Delegation of Authority Under Section 1604(b) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019

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 to the Secretary of Defense and the Secretary of Commerce the authority to transmit to the Congress the plan required by section 1604(b) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Public Law 115–232).

The delegation in this memorandum shall apply to any provision of any future public law that is the same or substantially the same as the provision referenced in this memorandum.

The Secretary of Defense is authorized and directed to publish this memorandum in the Federal Register.

THE WHITE HOUSE,
Washington, October 16, 2018
LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

Last List October 18, 2018

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly enacted public laws. To subscribe, go to http://listserv.gsa.gov/archives/publaws-l.html

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. PENS cannot respond to specific inquiries sent to this address.