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

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2015–17–04, which applied to certain Bombardier, Inc., Model CL–600–2C10 (Regional Jet Series 700, 701, & 702), Model CL–600–2D15 (Regional Jet Series 705), and Model CL–600–2D24 (Regional Jet Series 900) airplanes. AD 2015–17–04 required replacement of left and right fixed control rods and lever assemblies of the elevator control system. This AD adds a detailed visual inspection of the key washers and self-locking nuts of the elevator control linkages and corrective actions if necessary. This AD was prompted by reports of a disconnect between the elevator lever and control rod. The AD does not require operators, * * * [regardless of previously accomplished actions], to perform a detailed visual inspection for the correct installation of the tab washers having part number BA698–93726–3. The NPRM proposed to continue to require replacement of left and right fixed control rods and lever assemblies of the elevator control system. The NPRM also proposed to require a detailed visual inspection of the key washers and self-locking nuts of the elevator control linkages and corrective actions if necessary. We are issuing this AD to prevent a disconnect between the elevator lever and control rod, which could lead to uncommanded elevator movement of the associated control surface, a large difference between the position of the left and the right elevator control surfaces, and consequent reduced controllability of the airplane and degradation of the structural integrity of the horizontal stabilizer.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2014–44R1, dated October 6, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Bombardier, Inc., Model CL–600–2C10 (Regional Jet Series 700, 701, & 702), Model CL–600–2D15 (Regional Jet Series 705), and Model CL–600–2D24 (Regional Jet Series 900) airplanes. The MCAI states: During an engineering review of the Elevator Control system, it was discovered that a disconnect between the elevator lever and control rod could lead to an uncommanded elevator movement of the associated control surface. This uncommanded movement may cause a large difference between the position of the left and the right elevator control surface resulting in reduced controllability of the airplane and compromised structural integrity of the horizontal stabilizer. This [Canadian] AD mandates the replacement of the existing elevator lever assemblies and control rods with newly designed ones, which will prevent a disconnect between the components of the elevator control system should a failure occur.

Revision 1 of this [Canadian] AD is issued to require operators, * * * [regardless of previously accomplished actions], to perform a detailed visual inspection for the correct installation of the tab key washers and to re-torque the nut(s) [and corrective actions that include bending one tab of the key washer on a flat surface of the self-locking nut] if the tab key washer(s) does not have one tab bent on a flat surface of the self-locking nut.

For further information contact:


Supplementary information:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2015–17–04, Amendment 39–18237 (80 FR 50556, August 20, 2015) (“AD 2015–17–04”). AD 2015–17–04 applied to certain Bombardier, Inc., Model CL–600–2C10 (Regional Jet Series 700, 701, & 702), Model CL–600–2D15 (Regional Jet Series 705), and Model CL–600–2D24 (Regional Jet Series 900) airplanes. The NPRM published in the Federal Register on May 11, 2018 (83 FR 21966). The NPRM was prompted by reports of a disconnect between the elevator lever and control rod and a report indicating that certain revisions of the service information were missing instructions for proper installation of the key washers having part number BA698–93726–3. The NPRM proposed to continue to require replacement of left and right fixed control rods and lever assemblies of the elevator control system. The NPRM also proposed to require a detailed visual inspection of the key washers and self-locking nuts of the elevator control linkages and corrective actions if necessary. We are issuing this AD to prevent a disconnect between the elevator lever and control rod, which could lead to uncommanded elevator movement of the associated control surface, a large difference between the position of the left and the right elevator control surfaces, and consequent reduced controllability of the airplane and degradation of the structural integrity of the horizontal stabilizer.

The MCAI states: During an engineering review of the Elevator Control system, it was discovered that a disconnect between the elevator lever and control rod could lead to an uncommanded elevator movement of the associated control surface. This uncommanded movement may cause a large difference between the position of the left and the right elevator control surface resulting in reduced controllability of the airplane and compromised structural integrity of the horizontal stabilizer. This [Canadian] AD mandates the replacement of the existing elevator lever assemblies and control rods with newly designed ones, which will prevent a disconnect between the components of the elevator control system should a failure occur.

Revision 1 of this [Canadian] AD is issued to require operators, * * * [regardless of previously accomplished actions], to perform a detailed visual inspection for the correct installation of the tab key washers and to re-torque the nut(s) [and corrective actions that include bending one tab of the key washer on a flat surface of the self-locking nut] if the tab key washer(s) does not have one tab bent on a flat surface of the self-locking nut.

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Vol. 83, No. 187
Wednesday, September 26, 2018

Comments
We gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA’s response to each comment. The Air Line Pilots Association, International (ALPA) reviewed and expressed support for the NPRM.

Request To Clarify Required Actions in Paragraph (h) of the Proposed AD
Endeavor Air and SkyWest Airlines requested that we clarify paragraph (h) of the proposed AD to specify Part B of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–062, Revision E, dated June 8, 2017. The commenters pointed out that the Accomplishment Instructions are divided into two parts, Part A and Part B. The commenters also mentioned that Part A of the Accomplishment Instructions contains modification procedures (specified in paragraph (g) of the proposed AD) and Part B contains inspection requirements (specified in paragraph (h) of the proposed AD).

We agree to clarify as suggested by the commenter and have revised paragraphs (g) and (h) of this AD accordingly.

Request To Clarify Credit for Actions Accomplished Using Bombardier Service Non-Incorporated Engineering Order (SNIEO)
Endeavor Air requested that we clarify paragraph (i)(2) of the proposed AD to state that Bombardier SNIEO KBA670–93707 S02, dated July 21, 2015, can be accomplished concurrently or subsequently with the service information specified in paragraph (i)(2)(i) or (i)(2)(ii) of the proposed AD. The commenter pointed out that the level of safety is equivalent if the actions specified in Bombardier SNIEO KBA670–93707 S02, dated July 21, 2015, are accomplished subsequently to the actions specified in the service information specified in paragraph (i)(2)(i) or (i)(2)(ii) of the proposed AD.

We agree with the commenter for the reasons provided and have revised paragraph (i)(2) of this AD accordingly.

Request To Provide Credit for Actions Previously Accomplished
Endeavor Air requested that we provide credit for accomplishing the actions specified in paragraph (h) of the proposed AD prior to the effective date of this AD in accordance with Part B of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–062, Revision E, dated June 8, 2017.

We acknowledge the commenter’s requests and agree to clarify. Paragraph (f) of this AD states to accomplish the required actions within the compliance times specified, “unless already done.” Therefore, if operators have accomplished the actions required for compliance with this AD before the effective date of this AD, no further action is necessary. We have not revised this AD in this regard.

Conclusion
We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. We have determined that these minor changes:

• Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
• Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51
Bombardier, Inc., has issued Service Bulletin 670BA–27–062, Revision E, dated June 8, 2017. This service information describes procedures for replacing the elevator lever assemblies and control rods, and a detailed visual inspection of the key washers and self-locking nuts of the elevator control linkages and corrective actions, which include bending the tab of the key washers and re-torquing the self-locking nuts.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance
We estimate that this AD affects 549 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

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<tbody>
<tr>
<td>Replacement of fixed control rods and lever assemblies (retained actions from AD 2015–17–04). Detailed visual inspection of the key washers and self-locking nuts (new action).</td>
<td>14 work-hours × $85 per hour = $1,190 ..........</td>
<td>$6,712</td>
<td>$7,902</td>
<td>$4,338,198</td>
</tr>
<tr>
<td></td>
<td>3 work-hours × $85 per hour = $255 ..........</td>
<td>0</td>
<td>255</td>
<td>139,995</td>
</tr>
</tbody>
</table>

Authority for This Rulemaking
Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency’s authority.

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

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.
Regulatory Findings

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

For the reasons discussed above, I certify that this AD:
1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

§ 39.13 [Amended]

§ 39.13 (Amended) 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2015–17–04, Amendment 39–18237 (80 FR 50556, August 20, 2015), and adding the following new AD:


(a) Effective Date

This AD is effective October 31, 2018.

(b) Affected ADs


(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.


(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Reason

This AD was prompted by reports of a disconnect between the elevator lever and control rod and a report indicating that certain revisions of the service information were missing instructions for proper installation of the key washers having part number BA698–93726–3. We are issuing this AD to prevent a disconnect between the elevator lever and control rod, which could lead to uncommanded elevator movement of the associated control surface, a large difference between the position of the left and right elevator control surfaces, and consequent reduced controllability of the airplane and degradation of the structural integrity of the horizontal stabilizer.

(f) Compliance

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

(g) Retained Replacement of Elevator Lever Assemblies and Control Rods, With Revised Service Information

This paragraph restates the requirements of paragraph (g) of AD 2015–17–04, with revised service information. Within 9,200 flight hours or 5 years, whichever occurs first, after September 24, 2015 (the effective date of AD 2015–17–04): Replace the left and right fixed control rods and lever assemblies of the elevator control system with newly designed control rods and lever assemblies, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–062, Revision C, dated February 13, 2015, or Paragraph A of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–062, Revision E, dated June 8, 2017. After the effective date of this AD, only Part A of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–062, Revision E, dated June 8, 2017, may be used.

(h) New Requirement of This AD: Detailed Visual Inspection and Corrective Actions

Within 8,800 flight hours after the effective date of this AD, do a detailed visual inspection of the key washers and self-locking nuts of the elevator control linkages, and do all applicable corrective actions, in accordance with Part B of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–062, Revision E, dated June 8, 2017. Do all applicable corrective actions before further flight.

(i) Credit for Previous Actions

1. This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 670BA–27–062, dated December 12, 2013; Bombardier Service Bulletin 670BA–27–062, Revision D, dated October 10, 2014; or Bombardier Service Bulletin 670BA–27–062, Revision D, dated December 1, 2015. This service information is not incorporated by reference in this AD.

2. This paragraph provides credit for actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraph (i)(2)(i) or (ii)(2)(ii) of this AD, provided Bombardier Service Non-Incorporated Engineering Order (SNEIO) KBA670–93707 S02, dated July 21, 2015, was done concurrently with or subsequently to the service information specified in paragraph (ii)(2)(i) or (ii)(2)(ii) of this AD.


3. This paragraph provides credit for actions required by paragraph (h) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 670BA–27–062, Revision D, dated December 1, 2015. This service information is not incorporated by reference in this AD.

(j) Other FAA AD Provisions

(1) Alternative Methods of Compliance (AMOCs): The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; fax: 516–794–5531.

(i) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/ certificate holding district office.

(ii) AMOCs approved previously for AD 2015–17–04, are approved as AMOCs for the corresponding provisions of this AD.

(2) Contacting the Manufacturer: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.’s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2014–44R1, dated October 6, 2017, for related information. This MCAI may be

(2) For more information about this AD, contact Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7318; fax: 516–794–5531.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(4) and (l)(5) of this AD.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on October 31, 2018.


(ii) Reserved.

(4) For Bombardier, Inc. service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free phone: 1–866–538–1247 or direct-dial phone: 1–514–855–2999; fax: 514–855–7401; email: ac.yul@aoero.bombardier.com; internet: http://www.bombardier.com.

(5) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to:

Issued in Des Moines, Washington, on September 7, 2018.

Michael Kaszycyki,
Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–20350 Filed 9–25–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION
 Federal Aviation Administration

14 CFR Part 39


RIN 2120–AA64

Airworthiness Directives; 328 Support Services GmbH (Type Certificate Previously Held by AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all 328 Support Services GmbH Model 328–100 and –300 airplanes. This AD was prompted by reports indicating corrosion on the horizontal stabilizer bearing supports at the contact surface to the horizontal stabilizer rear spar. This AD requires inspections for corrosion and any other damage (i.e., cracking and chafing) of the horizontal stabilizer rear bearing supports, replacement of the affected horizontal stabilizer rear bearing supports if necessary, and modification of the horizontal stabilizer rear spar. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 31, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of October 31, 2018.

ADDRESSES: For service information identified in this final rule, contact 328 Support Services GmbH, Global Support Center, P.O. Box 1252, D–82231 Wessling, Federal Republic of Germany; telephone +49 8153 88111 6666; fax +49 8153 88111 6665; email gsc.op@328support.de; internet http://www.328support.de. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2018–0503.

Examining the AD Docket

You may examine the AD docket on the internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2018–0503; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:
Todd Thompson, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3228.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all 328 Support Services GmbH Model 328–100 and –300 airplanes. The NPRM published in the Federal Register on June 7, 2018 (83 FR 26389).

The NPRM was prompted by reports indicating corrosion on the horizontal stabilizer bearing supports at the contact surface to the horizontal stabilizer rear spar. The NPRM proposed to require inspections for corrosion and any other damage (i.e., cracking and chafing) of the horizontal stabilizer rear bearing supports, replacement of the affected horizontal stabilizer rear bearing supports if necessary, and modification of the horizontal stabilizer rear spar.

We are issuing this AD to address corrosion on the horizontal stabilizer rear bearing supports and rear spar, which could lead to failure of the fitting and loss of one load path of the horizontal stabilizer attachment, and possibly result in reduced controllability of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2017–0239, dated November 30, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for all 328 Support Services GmbH Model 328–100 and –300 airplanes. The MCAI states:

Occurrences were reported on horizontal stabilizer bearing supports being found corroded at the contact surface to the horizontal stabilizer rear spar. The corroded area was at the lower flange position, which is connected to the stabilizer rear spar and not visible without detachment of the fitting. Investigation determined that the corrosion is
triggered by galvanic effect, due to a direct contact between the horizontal stabilizer rear spar, made from CFRP (carbon fibre reinforced plastic), and the aluminium rear attachment fitting.

This condition, if not detected and corrected, could lead to failure of the fitting and loss of one load path of the horizontal stabilizer attachment, possibly resulting in reduced control of the airplane.

To address this potential unsafe condition, 328 Support Services GmbH (328 SSG) issued Service Bulletin (SB) SB–328–55–557 and SB–328J–55–324 to provide instructions for inspection of the affected area, replacement of the parts, and modification to improve corrosion behaviour by incorporating of glass fibre layer.

For the reasons described above, this [EASA] AD requires a one-time inspection [detailed visual inspection and an eddy current inspection for chafing and corrosion] of the horizontal stabilizer rear bearing supports, and, depending on findings, accomplishment of applicable corrective action(s) [replacement of the affected horizontal stabilizer rear bearing supports]. This [EASA] AD also requires a modification of the horizontal stabilizer rear spar, irrespective of findings.


Comments

We gave the public the opportunity to participate in developing this final rule. We received no comments on the NPRM or on the determination of the cost to the public.

New Service Information

We received 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 2, dated May 24, 2018; and 328 Support Services GmbH Service Bulletin SB–328J–55–324, Revision 2, dated May 24, 2018. We referred to 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 1, dated February 1, 2018; and 328 Support Services GmbH Service Bulletin SB–328J–55–324, Revision 1, dated February 1, 2018; as the appropriate sources of service information for the actions specified in the proposed AD. Revision 2 of the service information corrects spelling errors and adds alternative parts. No additional work is needed if the actions specified in the earlier revisions of the service information have been done.

We have revised this AD to refer to 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 2, dated May 24, 2018; and 328 Support Services GmbH Service Bulletin SB–328J–55–324, Revision 2, dated May 24, 2018, as the appropriate sources of service information for accomplishing the required actions. We have also added 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 1, dated February 1, 2018; and 328 Support Services GmbH Service Bulletin SB–328J–55–324, Revision 1, dated February 1, 2018, to paragraph (j) of this AD in order to give credit for accomplishing actions specified in Revision 1 of the service information.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes.

We have determined that these minor changes:
- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information Under 1 CFR Part 51

328 Support Services GmbH has issued Service Bulletin SB–328–55–557, Revision 2, dated May 24, 2018; and Service Bulletin SB–328J–55–324, Revision 2, dated May 24, 2018. This service information describes procedures for a detailed visual inspection and an eddy current inspection for corrosion and any other damage (i.e., cracking and chafing) of the horizontal stabilizer rear bearing supports, modification of the horizontal stabilizer rear spar, and replacement of the affected horizontal stabilizer rear bearing supports if necessary. These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance

We estimate that this AD affects 27 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

### ESTIMATED COSTS

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detailed visual inspection and eddy current inspection</td>
<td>4 work-hours × $85 per hour = $340 ..........</td>
<td>$0</td>
<td>$340</td>
<td>$9,180</td>
</tr>
<tr>
<td>Modification ..................................................</td>
<td>16 work-hours × $85 per hour = $1,360 ......</td>
<td>0</td>
<td>1,360</td>
<td>36,720</td>
</tr>
</tbody>
</table>

We estimate the following costs to do any necessary replacement that would be required based on the results of the inspection. We have no way of determining the number of aircraft that might need this replacement:

### ON-CONDITION COSTS

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Replacement ...........</td>
<td>24 work-hours × $95 per hour = $2,040 ..........</td>
<td>*</td>
<td>$2,040</td>
<td></td>
</tr>
</tbody>
</table>

*We have received no definitive data that would enable us to provide parts cost estimates for the on-condition action specified in this AD.*

### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency’s authority.
We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: “General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

(1) Is not a “significant regulatory action” under Executive Order 12866, (2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

§ 39.13 [Amended]

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


(a) Effective Date

This AD is effective October 31, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all 328 Support Services GmbH (Type Certificate previously held by AvCraft Aerospace GmbH; Fairchild Dornier GmbH; Dornier Luftfahrt GmbH) Model 328–100 and –300 airplanes, certified in any category.

(d) Subject

Air Transport Association (ATA) of America Code 55, Stabilizers.

(e) Reason

This AD was prompted by reports of corrosion on the horizontal stabilizer bearing supports at the contact surface to the horizontal stabilizer rear spar. We are issuing this AD to address corrosion on the horizontal stabilizer bearing supports and rear spar and rear spar, which could lead to failure of the fitting and loss of one load path of the horizontal stabilizer attachment, and possibly result in reduced controllability of the airplane.

(f) Compliance

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

(g) Inspection and Modification

(1) At the applicable time specified in paragraph (g)(3)(i) or (g)(3)(ii) of this AD, do a detailed visual inspection and an eddy current inspection for corrosion and any other damage (i.e., cracking and chafing) of the horizontal stabilizer rear bearing supports in accordance with the Accomplishment Instructions of 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 2, dated May 24, 2018 (for Model 328–100 airplanes); or 328 Support Services GmbH Service Bulletin SB–328–55–324, Revision 2, dated May 24, 2018 (for Model 328–300 airplanes); as applicable.

(2) At the applicable time specified in paragraph (g)(3)(i) or (g)(3)(ii) of this AD, modify the horizontal stabilizer rear spar in accordance with the Accomplishment Instructions of 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 2, dated May 24, 2018 (for Model 328–100 airplanes); or 328 Support Services GmbH Service Bulletin SB–328–55–324, Revision 2, dated May 24, 2018 (for Model 328–300 airplanes); as applicable.

(iii) For Group 2 airplanes, S/Ns 102 through 3224 inclusive, as identified in 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 2, dated May 24, 2018 (for Model 328–100 airplanes); or 328 Support Services GmbH Service Bulletin SB–328–55–324, Revision 2, dated May 24, 2018 (for Model 328–300 airplanes); as applicable: Within 5,000 flight hours or 30 months, whichever occurs first after the effective date of this AD.

(i) For Group 1 airplanes, serial numbers (S/Ns) 1005 through 1031 inclusive, as identified in 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 2, dated May 24, 2018 (for Model 328–100 airplanes); or 328 Support Services GmbH Service Bulletin SB–328–55–324, Revision 2, dated May 24, 2018 (for Model 328–300 airplanes); as applicable.

(j) Credit for Previous Actions

As of the applicable time specified in paragraph (i)(1) or (i)(2) of this AD, no person may install a horizontal stabilizer rear bearing support, part number 001B551A1441000, on any airplane.

(1) For Group 1 airplanes, S/Ns 1005 through 1031 inclusive, as identified in 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 2, dated May 24, 2018 (for Model 328–100 airplanes); or 328 Support Services GmbH Service Bulletin SB–328–55–324, Revision 2, dated May 24, 2018 (for Model 328–300 airplanes); as applicable:

(b) Corrective Action

If, during the inspections required by paragraph (g) of this AD, corrosion or any other damage (i.e., cracking and chafing) is detected, before further flight, replace the affected horizontal stabilizer rear bearing supports in accordance with the Accomplishment Instructions of 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 2, dated May 24, 2018 (for Model 328–100 airplanes); or 328 Support Services GmbH Service Bulletin SB–328–55–324, Revision 2, dated May 24, 2018 (for Model 328–300 airplanes); as applicable.

Parts Installation Prohibition

As of the applicable time specified in paragraph (i)(1) or (i)(2) of this AD, no person may install a horizontal stabilizer rear bearing support, part number 001B551A1441000, on any airplane.

(1) For Group 1 airplanes, S/Ns 1005 through 1031 inclusive, as identified in 328 Support Services GmbH Service Bulletin SB–328–55–557, Revision 2, dated May 24, 2018 (for Model 328–100 airplanes); or 328 Support Services GmbH Service Bulletin SB–328–55–324, Revision 2, dated May 24, 2018 (for Model 328–300 airplanes); as applicable:

(j) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraphs (g) and (h) of this AD, if those actions were performed before the effective date of this AD using 328 Support Services GmbH Service Bulletin SB–328–55–557, dated September 1, 2017; or 328 Support Services GmbH Service Bulletin SB–
SUMMARY: We are superseding Airworthiness Directive (AD) 2010–25–06, which applied to certain The Boeing Company Model 737–200, –300, –400, and –500 series airplanes. AD 2010–25–06 required repetitive inspections for cracking of certain fuselage frames and stub beams, and corrective actions if necessary. AD 2010–25–06 also provided for an optional repair, which terminated the repetitive inspections. For airplanes on which a certain repair was done, AD 2010–25–06 also required repetitive inspections for cracking of certain fuselage frames and stub beams, and corrective actions if necessary. This AD retains the actions required by AD 2010–25–06 and expands the inspection area. This AD was prompted by additional cracking found in areas not covered by the inspections in AD 2010–25–06. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective October 31, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of October 31, 2018.


Examining the AD Docket
You may examine the AD docket on the internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2018–0412; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD Docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:
Discussion
We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2010–25–06, Amendment 39–16539 (75 FR 81409, December 28, 2010) (“AD 2010–25–06”). AD 2010–25–06 applied to certain Model 737–200, –300, –400, and –500 series airplanes. The NPRM published in the Federal Register on May 15, 2018 (83 FR 22422). The NPRM was prompted by additional cracking found in areas not covered by the inspections in AD 2010–25–06. The NPRM proposed to retain the actions required by AD 2010–25–06 and expand the inspection area. We are issuing this AD...
to address fatigue cracking of certain fuselage frames and stub beams and possible severed frames, which could result in reduced structural integrity of the frames. This reduced structural integrity can increase loading in the fuselage skin, which will accelerate skin crack growth and could result in rapid decompression of the fuselage.

Comments

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

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing the supplemental type certificate (STC) ST01219SE does not affect the actions specified in the NPRM. We agree with the commenter. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) of this AD and added paragraph (c)(2) to this AD to state that installation of STC ST01219SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST01219SE is installed, a “change in product” alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Request To Clarify Compliance Language

Boeing asked that the compliance language in paragraphs (g), (h), (i), (j) and (k) of the proposed AD be changed since there are multiple conditions and compliance times specified in paragraph 1.E., “Compliance” of the referenced service information. Boeing asked that the wording in these paragraphs be changed from “at the applicable time” specified in tables 1, 2, 3, 4, 5, and 9, respectively, to “at the applicable condition and time” specified in tables 1, 2, 3, 4, 5, and 9, respectively. Boeing stated that these changes would provide clarification.

Although we do not agree to revise this AD as requested by the commenter, we agree to clarify the compliance language. The phrase “at the applicable time” means the compliance time associated with a given condition, as specified in the applicable table in paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017. We have not changed this AD in this regard.

Addition of Omitted Word

We inadvertently omitted the word “in” prior to the word “table” in the phrase “...the applicable time specified table...” in certain sentences in paragraphs (g), (h), (i), and (j) of the proposed AD. We have revised the applicable sentences in paragraphs (g), (h), (i), and (j) of this AD to read “...the applicable time specified in table...”

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously, and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017. This service information describes procedures for detailed and eddy current inspections of the fuselage frame and over wing stub beam at body station (BS) 616, BS 639, and BS 597 or BS 601, and buttock line (BL) 45.5 floor beam web at the BS 639 stub beam attachment, and related investigative and corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

Costs of Compliance

We estimate that this AD affects 67 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

### ESTIMATED COSTS FOR REQUIRED ACTIONS

<table>
<thead>
<tr>
<th>Action</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
<th>Cost on U.S. operators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspections</td>
<td>Up to 67 work-hours x $85 per hour = $5,695 per inspection cycle.</td>
<td>$0</td>
<td>Up to $5,695 per inspection cycle.</td>
<td>Up to $381,565 per inspection cycle.</td>
</tr>
</tbody>
</table>

We estimate the following costs to do certain necessary repairs/replacements that would be required based on the results of the inspections. We have no way of determining the number of aircraft that might need these repairs/replacements:

### ON-CONDITION COSTS

<table>
<thead>
<tr>
<th>Action **</th>
<th>Labor cost</th>
<th>Parts cost</th>
<th>Cost per product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repairs/replacements</td>
<td>Up to 76 work-hours x $85 per hour = $6,460</td>
<td>*</td>
<td>Up to $6,460.</td>
</tr>
</tbody>
</table>

* All required parts are supplied by the operator. This cost is minimal, and we have no way to determine what an operator would pay for these parts.

** We have received no definitive data that would enable us to provide cost estimates for certain other repairs specified in this AD.

### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency’s authority.
We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, “General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

§ 39.13 [Amended]

§ 39.13 lists the Airworthiness Directives (AD) 2010–25–06, Amendment 39–16539 (75 FR 81409, December 28, 2010), and adding the following new AD:


(a) Effective Date

This AD is effective October 31, 2018.

(b) Affected ADs


(c) Applicability

(1) This AD applies to The Boeing Company Model 737–500, 737–600, and –500 series airplanes, certified in any category, as identified in Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017.

(2) Installation of Supplemental Type Certificate (STC) ST01219SE (http://reg.faa.gov/Regulatory_and_Guidance/Library/sttc negotiate or ST012179SE.pdf) does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST012179SE is installed, a “change in product” alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by the detection of fatigue cracks at certain frame sections, in addition to stub beam cracking, caused by high flight cycle stresses from both pressurization and maneuver loads and additional cracking found in areas not covered by the inspections in AD 2010–25–06. We are issuing this AD to address fatigue cracking of certain fuselage frames and stub beams and possible severed frames, which could result in reduced structural integrity of the frames. This reduced structural integrity can increase loading in the fuselage skin, which will accelerate skin crack growth and could result in rapid decompression of the fuselage.

(f) Compliance

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

(g) Repetitive Inspections of Body Stations 616 and 639 Frames and Stub Beams and Corrective Actions

At the applicable time specified in table 1 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017: Do a detailed or high frequency eddy current (HFEC) inspection for cracking of the body station (BS) 616 and 639 frames and stub beams and do all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, except as required by paragraph (m)(1) of this AD. Do all applicable related investigative and corrective actions before further flight. Therefore, repeat the inspection at the applicable time specified in table 1 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017.

(h) Repetitive Post-Repair Inspections of Body Stations 616 and 639 Frames and Integral Stub Beams and Corrective Actions

At the applicable time specified in table 2 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017: Do the inspections required by paragraphs (b)(1) and (b)(2) of this AD; or the inspection required by paragraph (h)(3) of this AD; as applicable, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, except as required by paragraph (m)(1) of this AD. Do all applicable related investigative and corrective actions before further flight. Therefore, repeat the inspection at the applicable time specified in table 2 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017.

(1) Do a low frequency eddy current (LFEC) inspection of the web, and an HFEC inspection of the inner and outer chord common to the upper end fastener rows of the web splice doubler for cracking.

(2) Do the inspection specified in paragraph (h)(2)(i) or (h)(2)(ii) of this AD.

(i) Do a detailed inspection of the replacement frame section for cracking.

(ii) Do an HFEC and LFEC inspection of the replacement frame section for cracking.

(3) Do a detailed or HFEC inspection of the replacement stub beam for cracking.

(i) Repetitive Inspections of Buttock Line 45.5 Longitudinal Floor Beam Web at Body Station 639 Stub Beam Attachment and Corrective Actions

For Group 1 and Group 2 airplanes as identified in Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, at the time specified in table 3 or table 4, as applicable, of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, except as required by paragraph (m)(2) of this AD: Do the inspections required by paragraph (i)(1) and (i)(2) of this AD and all applicable corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert
Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, except as required by paragraph (m)(1) of this AD. Do all applicable corrective actions before further flight. Thereafter, repeat the inspections at the time specified in table 3 or table 4, as applicable, of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017.

(1) Do an open-hole HFEC inspection for cracking of the buttock line (BL) 45.5 longitudinal floor beam web at each fastener hole common to the stub beam attachment angle.

(2) Do an HFEC surface inspection for cracking of the BL 45.5 longitudinal floor beam web around the fastener head/tail at each fastener location common to the backup strap.

(j) Repetitive Post-Repair Inspections of Buttline Line 45.5 Longitudinal Floor Beam Web at Body Station 639 and Corrective Actions

For Group 2 airplanes as identified in Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, at the applicable time specified in table 5 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, except as required by paragraph (m)(2) of this AD: Do the inspections required by paragraphs (j)(1) and (j)(2) of this AD and all applicable corrective actions, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, except as required by paragraph (m)(1) of this AD. Do all applicable corrective actions before further flight. Thereafter, repeat the inspections at the applicable time specified in table 5 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017.

(1) Do an open-hole HFEC inspection for cracking of the BL 45.5 longitudinal floor beam web filler at each fastener hole common to the stub beam attachment angle.

(2) Do an HFEC surface inspection for cracking of the BL 45.5 longitudinal floor beam web filler around the fastener head/tail at each fastener location common to the backup strap.

(k) Repetitive Inspections for Cracking of BS 616 Machined Stub Beam Upper Chord and Corrective Actions

For Group 2 and Group 3 airplanes as identified in Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, at the applicable time specified in table 9 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017, except as required by paragraph (m)(2) of this AD: Do detailed and medium frequency eddy current subsurface inspections for cracking of the BS 616 machined stub beam upper chord, and all applicable corrective actions, except as required by paragraph (m)(1) of this AD. Do all applicable corrective actions before further flight. Thereafter, repeat the inspections at the applicable time specified in table 9 of paragraph 1.E., “Compliance,” of Boeing Alert Service Bulletin 737–53A1254, Revision 3, dated November 13, 2017.
feet above the surface at Glen Ullin Regional Airport, Glen Ullin, ND. Controlled airspace is necessary to accommodate new standard instrument approach procedures developed at Glen Ullin Regional Airport, for the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Effective 0901 UTC, November 8, 2018. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments, can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741-6030, or go to https://www.archives.gov/federal-register/cfr/ibr-locations.html.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Rebecca Shelby, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5857.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace extending upward from 700 feet above the surface at Glen Ullin Regional Airport, Glen Ullin, ND to support IFR operations at the airport.

History

On May 21, 2018, the FAA published a notice of proposed rulemaking in the Federal Register (83 FR 23381) for Docket No. FAA–2018–0312, to establish Class E airspace extending upward from 700 feet above the surface at Glen Ullin Regional Airport, Glen Ullin, ND. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the ADDRESSES section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes Class E airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Glen Ullin Regional Airport, Glen Ullin, ND, to accommodate new standard instrument approach procedures developed for the airport, for the safety and management of instrument flight rules (IFR) operations. Controlled airspace is necessary.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, “Environmental Impacts: Policies and Procedures,” paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

AGL ND E5 Glen Ullin, ND [New]

Glen Ullin Regional Airport, WI (Lat. 46°48′52″ N, long. 101°51′55″ W) That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Glen Ullin Regional Airport.

Issued in Fort Worth, Texas, on September 18, 2018.

Walter Tweedy,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2018–20870 Filed 9–25–18; 8:45 am] COMMBUS

BILLING CODE 4910–13–P
DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 744

[Docket No. 180910826–8826–01]

RIN 0694–AH63

Addition of Certain Entities to the Entity List, Revision of an Entry on the Entity List and Removal of an Entity From the Entity List

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This final rule amends the Export Administration Regulations (EAR) by adding fourteen entities to the Entity List. These fourteen entities have been determined by the U.S. Government to be acting contrary to the national security or foreign policy interests of the United States and will be listed on the Entity List under the destinations of Belarus, Iran, Russia, and Singapore. This rule also modifies one entry on the Entity List under the destination of the United Arab Emirates. Lastly, this rule removes one entity under the destination of Hong Kong from the Entity List. The removal is made in connection with a request for removal BIS received pursuant to the EAR and a review of information provided in that request.

DATES: This rule is effective September 26, 2018.

FOR FURTHER INFORMATION CONTACT:
Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482–5991, Email: ERC@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

The Entity List (15 CFR, Subchapter C, part 744, Supplement No. 4) identifies entities reasonably believed to be involved, or to pose a significant risk of being or becoming involved, in activities contrary to the national security or foreign policy interests of the United States. The Export Administration Regulations (EAR) (15 CFR, Subchapter C, parts 730–774) imposes additional license requirements on, and limits the availability of most license exceptions for, exports, reexports, and transfers (in-country) to listed entities. The license review policy for each listed entity is identified in the “License review policy” column on the Entity List, and the impact on the availability of license exceptions is described in the relevant Federal Register notice adding entities to the Entity List. BIS places entities on the Entity List pursuant to part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The End-User Review Committee (ERC), composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy and, where appropriate, the Treasury, makes all decisions regarding additions to, removals from, or other modifications to the Entity List. The ERC makes all decisions to add an entry to the Entity List by majority vote, and makes all decisions to remove or modify an entry by unanimous vote.

ERC Entity List Decisions

Additions to the Entity List

This rule implements the decision of the ERC to add fourteen entities to the Entity List. The addition of these fourteen entities involves sixteen Entity List entries, as one of the entities being added has locations in three destinations. The fourteen entities are being added based on § 744.11 (License requirements that apply to entities acting contrary to the national security or foreign policy interests of the United States) of the EAR. The ERC determined that the conduct of these fourteen entities raises sufficient concern that prior review of exports, reexports or transfers (in-country) of all items subject to the EAR involving these entities, and the possible imposition of license conditions or license denials on shipments to the persons, will enhance BIS’s ability to prevent violations of the EAR.

For thirteen of the fourteen entities described above that are being added to the Entity List, BIS imposes a license requirement for all items subject to the EAR and a license review policy of presumption of denial. For All Industrial Manufacturing (AIM) Pte Ltd., the entity added under Singapore, BIS imposes a license requirement for all items subject to the EAR and will exercise the license review policy set forth in subpart (d) of EAR § 744.2, a nuclear end-user and end-use based provision. For all fourteen entities, the license requirements apply to any transaction in which items are to be exported, reexported, or transferred (in-country) to any of the entities or in which such entities act as buyer, intermediate consignee, ultimate consignee, or end-user. In addition, no
license exceptions are available for exports, reexports, or transfers (in-country) to the entities being added to the Entity List in this rule. The acronym “a.k.a.” (also known as) is used in entries on the Entity List to identify aliases, thereby assisting exporters, reexporters and transferors in identifying entities on the Entity List.

This final rule adds the following fourteen entities to the Entity List, including one entity listed under three separate aliases, thereby assisting exporters, reexporters, or transfers (in-license exceptions are available for Iran and Russia).

Belarus

(1) Mohammad Ghassem Najafi, Unit 705, No. 103, Potbediteley Ave., Minsk, Belarus; and

(2) Nilco Group, a.k.a., the following one alias:

—Nilfam Khazar Co.
Unit 705, No. 103, Potbediteley Ave., Minsk, Belarus (see alternate addresses under Iran and Russia).

Iran

(1) Nilco Group, a.k.a., the following one alias:

—Nilfam Khazar Co.
Unit 6, No. 1, Mehr Alley, Gilan St., Boostan 2, Pasdaran Ave., Tehran, Iran (see alternate addresses under Belarus and Russia).

Russia

(1) AeroCompozit, Antonova Prospekt 1, Zavolzhsky District, Ulyanovsk, 432072, Russia;

(2) Divtechnotserwiss, a.k.a., the following five aliases:

—OOO Divtechnotserwiss;
—OOO Daiveticaonserwiss;
—OOO Daivtechnotserwiss;
—OOO NPPE DTS; and
—OOO DTS.
Ulitsa Zhleznovodskaya, 18/2 Litera A, Saint Petersburg, 199155, Russia;

(3) Federal State Unitary Enterprise Scientific Production Enterprise “GAMMA”,
Ul. Profsoyuznaya d. 78 str. 4, Moscow, 117393, Russia;

(4) Joint Stock Company Scientific-Research Institute “Vektor”,
Ul. Akademika Pavlova, d. 14–A, Saint Petersburg, 197376, Russia;

(5) Nilco Group, a.k.a., the following one alias:

—Nilfam Khazar Co.
Unit 439, 2 Mozhayskoe Road, Moscow, Russia (see alternate addresses under Belarus and Iran);

(6) Obinsk Research and Production Enterprise (ORPE), a.k.a., the following three aliases:

—ORPE Technologiya;
—ONPP Technologiya; and
—Obinsk Composite Materials Plant.
Kievskoe Shosse 15, Obinsk, 249031, Russia;

(7) Oceanos, 19/2 Esenina Street, Saint Petersburg, 194295, Russia; and 16/2 A–H Engelsa Prospect, Saint Petersburg, 195156, Russia;

(8) Open Joint Stock Company Aviadvigatel, a.k.a., the following one alias:

—AVI.
Komsomolsky Prospekt 93, Perm, 614990, Russia;

(9) Open Joint Stock Company Information Technology and Communication Systems, a.k.a., the following two aliases:

—OJSC Infoteks; and
—OJSC Infotecs.
Proezd Petrovsko-Razumovskii Star, d. 1/23 str. 1 Business Center “Vympel,” Moscow, 127287, Russia;

(10) Open Joint Stock Company Scientific and Production Corporation of Precision Instruments Engineering (NPK–SPP), a.k.a., the following one alias:

—OJSC RPC PSI.
Aviamotornaya Ulitsa 53, Moscow, 111024, Russia;

(11) Syrus Systems, 3–Y Novyy Pereulok, 5, Moscow, 107140, Russia; and

(12) Voronezh Scientific Research Institute “Vega”, a.k.a., the following two aliases:

—Voronezhsky Nauchno-Issledovatelskiy Institut “Vega”; and
—VNII “Vega”.
Moskovskiy Prospekt 7B, Voronezh, 394026, Russia.

Singapore

(1) All Industrial Manufacturing (AIM) Pte Ltd.,
4 Kaki Bukit Ave 1, #02–05, 417939, Singapore.

Modifications to the Entity List

This final rule implements the decision of the ERC to modify one existing entry, AdCom Systems, which was added to the Entity List under the designation of the United Arab Emirates on March 21, 2016 (81 FR 14958) for attempting to export Missile Technology Control Regime (MTCR) Category I unmanned aerial vehicles to countries that are not MTCR members. The ERC determined that AdCom Systems has been using two aliases, Sky Global Communications and Sky Global Communications Systems.

Consequently, BIS is revising the entry for AdCom Systems by adding two aliases and a new address.

United Arab Emirates

(1) AdCom Emirates, a.k.a., the following two aliases:

—Sky Global Communications; and
—Sky Global Communication Systems.

Industrial City of Abu Dhabi—ICAD1, Mussafah, Abu Dhabi, UAE; and #2 Mezzanine Level, Block 19, Sharq 40 Al Mourour Street, Abu Dhabi Island, Abu Dhabi, UAE.

Removal From the Entity List

This rule implements a decision of the ERC to remove Antony Emmanuel, an entity located in Hong Kong, from the Entity List on the basis of a removal request. The entry for Antony Emmanuel was added to the Entity List on October 22, 2008 (73 FR 54505). The ERC decided to remove this entry based on information BIS received pursuant to § 744.16 of the EAR and the review the ERC conducted in accordance with procedures described in Supplement No. 5 to part 744.

This final rule implements the decision to remove the following entity located in Hong Kong from the Entity List:

Hong Kong

(1) Antony Emmanuel,
No. 3 & 4, 12F Commercial VIP Building, 112–116 Canton Rd., Tsim Sha Tsui, Hong Kong.

Savings Clause

Shipments of items removed from eligibility for a License Exception or for export or reexport without a license (NLR) as a result of this regulatory action that were en route aboard a carrier to a port of export or reexport, on September 26, 2018, pursuant to actual orders for export or reexport to a foreign destination, may proceed to that destination under the previous eligibility for a License Exception or export or reexport without a license (NLR).

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018 (ECRA) (Title XVII, Subtitle B of Pub. L. 115–232), which provides the legal basis for BIS’s principal authorities and serves as the authority under which BIS issues this rule. As set forth in § 1768 of ECRA, all delegations, rules, regulations, orders, determinations, licenses, or other forms of
administrative action that have been made, issued, conducted, or allowed to become effective under the Export Administration Act of 1979 (50 U.S.C. 4601 et seq.) (as in effect prior to August 13, 2018) and as continued in effect pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et seq.) and Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013), and as extended by the Notice of August 8, 2018, 83 FR 39871 (August 13, 2018), or the Export Administration Regulations, and are in effect as of August 13, 2018, shall continue in effect according to their terms until modified, superseded, set aside, or revoked under the authority of ECRA.

Rulemaking Requirements

1. 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, distributive 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 determined to be not significant for purposes of Executive Order 12866. This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications, and carries a burden estimate of 43.8 minutes for a manual or electronic submission.

Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to Jasmeet.K.Seehra@omb.eop.gov, or by fax to (202) 395–7285.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. Pursuant to §762 of the Export Control Reform Act of 2018 (Title XVII, Subtitle B of Pub. L. 115–232), which was included in the John S. McCain National Defense Authorization Act for Fiscal Year 2019, this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. This action involves the removal of an entity from the Entity List. Removals from the Entity List involve interagency deliberation and result from review of public and non-public sources, including, where applicable, sensitive law enforcement information and classified information, and the measurement of such information against the Entity List removal criteria. This information is reviewed according to the procedures and criteria for evaluating removal requests from the Entity List, as set forth in 15 CFR 744.11, 15 CFR 744.16, and 15 CFR part 744, Supplement No. 5. For reasons of national security, BIS is not at liberty to provide to the public detailed information on which the ERC relies to make the decisions to remove these entities. In addition, the information included in a removal request is exchanged between the applicant and the ERC, which by law (§1761(h) of the ECRA), BIS is restricted from sharing with the public. Moreover, removal requests from the Entity List may contain confidential business information that is necessary for the extensive review conducted by the ERC.

6. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq., are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subjects in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 744—[AMENDED]

1. The authority citation for 15 CFR part 744 continues to read as follows:


2. Supplement No. 4 to part 744 is amended:

a. Under Belarus, by adding in alphabetical order, two Belarusian entities, “Mohammad Ghassem Najafi” and “Nilco Group”;

b. Under Hong Kong, by removing one Hong Kong entity, “Antony Emmanuel, No. 3 & 4, 12F Commercial VIP Building, 112–116 Canton Rd., Tsim Sha Tsui, Hong Kong”;

c. Under Iran, by adding in alphabetical order, one Iranian entity, “Nilco Group”;


e. Under Singapore, by adding in alphabetical order, one Singaporean entity, “All Industrial Manufacturing (AIM) Pte Ltd.”;

f. Under the United Arab Emirates, by revising Emirati entity, “AdCom Systems”.

The additions and revisions read as follows:
### SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST

<table>
<thead>
<tr>
<th>Country</th>
<th>Entity</th>
<th>License requirement</th>
<th>License review policy</th>
<th>Federal Register citation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BELARUS</strong></td>
<td>* Mohammad Ghassem Najafi, Unit 705, No. 103, Potbediteley Ave., Minsk, Belarus. *</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ...... 83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Nilco Group, a.k.a., the following one alias: * —Nilfam Khazar Co. Unit 705, No. 103, Potbediteley Ave., Minsk, Belarus (see alternate addresses under Iran and Russia.)</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ...... 83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
<td></td>
</tr>
<tr>
<td><strong>IRAN</strong></td>
<td>* Mohammad Ghassem Najafi, Unit 705, No. 103, Potbediteley Ave., Minsk, Belarus. *</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ...... 83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
<td></td>
</tr>
<tr>
<td></td>
<td>* Nilco Group, a.k.a., the following one alias: * —Nilfam Khazar Co. Unit 6, No. 1, Mehr Alley, Gilan St., Boosantan 2, Pasdaran Ave., Tehran, Iran (see alternate addresses under Belarus and Russia.)</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ...... 83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
<td></td>
</tr>
<tr>
<td><strong>RUSSIA</strong></td>
<td>* Mohammad Ghassem Najafi, Unit 705, No. 103, Potbediteley Ave., Minsk, Belarus. *</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ...... 83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
<td></td>
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<tr>
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<td>* Nilco Group, a.k.a., the following one alias: * —Nilfam Khazar Co. Unit 705, No. 103, Potbediteley Ave., Minsk, Belarus (see alternate addresses under Iran and Russia.)</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ...... 83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
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### SUPPLEMENT NO. 4 TO PART 744—ENTITY LIST—Continued

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<td>Obinsk Research and Production Enterprise (ORPE), a.k.a., the following three aliases: —ORPE Technologiya; —ONPP Technologiya; and —Obinsk Composite Materials Plant. Kievskoe Shosse 15, Obinsk, 249031, Russia.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
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<td>83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
</tr>
<tr>
<td></td>
<td>Oceanos, 19/2 Esenina Street, Saint Petersburg, 194295, Russia; and 16/2 A-H Engelsa Prospekt, Saint Petersburg, 195156, Russia.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ......</td>
<td>83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
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<tr>
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<td>Open Joint Stock Company Aviadvigatel, a.k.a., the following one alias: —AVI. Komsomolsky Prospekt 93, Perm, 614990, Russia.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ......</td>
<td>83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
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<td>Open Joint Stock Company Information Technology and Communication Systems, a.k.a., the following two aliases: —OJSC Infoteks; and —OJSC Infotecs. Proezd Petrovsko-Razumovski Star, d. 1/23 str. 1 Business Center &quot;Vympel,&quot; Moscow, 127287, Russia.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
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<td>83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
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<tr>
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<td>Open Joint Stock Company Scientific and Production Corporation of Precision Instruments Engineering (NPK-SPP), a.k.a., the following one alias: —OJC RPC PSI. Aviamotornyaya Ulitsa 53, Moscow, 111024, Russia.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ......</td>
<td>83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
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<td>Syrus Systems, 3–Y Novyy Pereulok, 5, Moscow, 107140, Russia.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ......</td>
<td>83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
</tr>
<tr>
<td></td>
<td>Voronezh Scientific Research Institute &quot;Vega&quot;; a.k.a., the following two aliases: —Voronezhskiy Nauchno-Issledovatelskiy Institut &quot;Vega&quot;; and —VNII Vega. Moskovskiy Prospekt 7B, Voronezh, 394026, Russia.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>Presumption of denial ......</td>
<td>83 FR [INSERT FR PAGE NUMBER 9/26/2018].</td>
</tr>
<tr>
<td></td>
<td>SINGAPORE .... All Industrial Manufacturing (AIM) Pte Ltd., 4 Kaki Bukit Ave 1, #02–05, 417939, Singapore.</td>
<td>For all items subject to the EAR. (See § 744.11 of the EAR.)</td>
<td>See 744.2(d) of the EAR</td>
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<td>UNITED ARAB EMIRATES.</td>
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I. Background

E.O. 13658, titled “Establishing a Minimum Wage for Contractors,” was issued on February 12, 2014. See 79 FR 9849. E.O. 13658 raised the hourly minimum wage for certain workers performing work on covered Federal contracts to $10.10 per hour in 2015, with annual inflation-based adjustments thereafter as determined by the Secretary of Labor (Secretary). Id. As of January 1, 2018, the E.O. 13658 minimum wage rate is $10.35 per hour. As of January 1, 2019, the E.O. 13658 minimum wage will be $10.60 per hour. See 83 FR 44906.1

E.O. 13658 and its implementing regulations established that this minimum wage requirement applies only to a “new contract” that qualifies as: (A) A procurement contract for construction covered under the Davis-Bacon Act (DBA); (B) a contract for services covered under the McNamara-O’Hara Service Contract Act (SCA); (C) a contract for concessions, including any concessions contract that the Department’s regulations at 29 CFR 4.133(b) exclude from the SCA; or (D) a contract with the Federal Government in connection with Federal property or lands and related to offering services for Federal employees, their dependents, or the general public. Further, this minimum wage requirement applies only when the Fair Labor Standards Act (FLSA), the SCA, or the DBA governs the workers’ wages. The October 7, 2014 final rule implementing E.O. 13658 applied to covered workers of contractors providing seasonal recreational services or seasonal recreational equipment rental on Federal lands under covered contracts. On May 25, 2018, President Donald J. Trump issued E.O. 13838, titled “Exemption from Executive Order 13658 for Recreational Services on Federal Lands.” See 83 FR 25341. Section 2 of E.O. 13838 amended E.O. 13658 to add language providing that the provisions of E.O. 13658 do not apply to federal contracts or contract-like instruments entered into “in connection with seasonal recreational services or seasonal recreational equipment rental.” The E.O. additionally stated that seasonal recreational services include “river running, hunting, fishing, horseback riding, camping, mountaineering activities, recreational ski services, and youth camps.” E.O. 13838 further specified that this exemption does not apply to “lodging and food services associated with seasonal recreational activities.”

E.O. 13838 explained that because of the nature of the industry, seasonal recreational workers have “irregular work schedules, a high incidence of overtime pay, and an unusually high turnover rate.” The order further explained that implementing E.O. 13658, therefore, threatened to significantly increase the cost of seasonal recreational services on Federal lands, while limiting the hours that recreational-service workers would be available to work. Thus, exempting these services from E.O. 13658 would help prevent job losses and ensure affordable guided tours for visitors to Federal lands.

E.O. 13838 requires executive departments and agencies to “promptly
take appropriate action to implement this exemption and to ensure that [their] regulations and agency guidance are consistent” with the E.O.

II. Basis and Purpose

A. Basis

The Department is updating 29 CFR 10.4 to conform to the requirements of E.O. 13838. The President issued E.O. 13838 pursuant to his authority under the Constitution and the Federal Property and Administrative Services Act (Procurement Act). 83 FR 25341. The Procurement Act authorizes the President to “prescribe policies and directives that [the President] considers necessary to carry out” the statutory purposes of ensuring “economical and efficient” government procurement and administration of government property. 40 U.S.C. 101, 121(a).

The Secretary has delegated his authority to implement E.O. 13658, and hence E.O. 13838, to the Administrator of the WHD. See Secretary’s Order 01–2014 (Dec. 19, 2014), 79 FR 77527 (published Dec. 24, 2014).

B. Purpose

The Department is promulgating this final rule to implement E.O. 13838’s exemption for seasonal recreational services and equipment rental. This action makes no substantive changes to E.O. 13658 or its implementing regulations beyond what E.O. 13838 addresses, as E.O. 13838 itself modified E.O. 13658 and directed Federal agencies and departments to implement that exemption. This action conforms E.O. 13658’s implementing regulations with the requirements of E.O. 13838. This will help ensure that parties contracting with the Federal Government are aware of the scope of coverage under E.O. 13658, as amended by E.O. 13838.

III. Discussion of the Final Rule

To incorporate E.O. 13838 into existing regulations, the Department is amending 29 CFR 10.4 to add a new subsection (g), containing language identical to that which E.O. 13838 inserted into E.O. 13658. New 29 CFR 10.4(g) will reflect that the requirements of E.O. 13658 no longer apply to special-use permits or similar instruments issued by the U.S. Forest Service or other Federal agencies for seasonal recreational outfitter services, seasonal recreational guide services, and other seasonal recreational services, or to permits or instruments issued for seasonal recreational equipment rental.

Consistent with the instruction in E.O. 13838, new 29 CFR 10.4(g) does not limit E.O. 13658’s coverage of lodging and food services associated with seasonal recreational services, even when seasonal recreational services or seasonal recreational equipment rental are also provided under the same contract. Thus, when a contract contains both exempt and covered services—say, services for equipment rental and also services for food and lodging—E.O. 13658 will continue to apply to the covered services (i.e., the contractor minimum wage would apply to the positions in food service and lodging, but not to the positions in equipment rental). In such circumstances, the E.O. minimum wage contract-clause in appendix A of 29 CFR part 10 should therefore be included in all covered contracts and solicitations for such contracts, as described in 29 CFR 10.3. In these instances, the contracting agency, in consultation with the contractor and WHD as needed, shall identify which services are covered and which are exempt from the requirements of E.O. 13658.

E.O. 13838 and new 29 CFR 10.4(g) do not affect the Department’s implementation, administration, or enforcement of the Final Rule implementing E.O. 13658 with respect to any contracts other than those exempted in whole or in part from coverage under E.O. 13658 and 29 CFR 10.4(g). They likewise do not affect contracting agencies’ implementation and administration of E.O. 13658 and its implementing regulations with respect to any contract other than those specifically described in E.O. 13838. E.O. 13838 and new 29 CFR 10.4(g) also do not limit or otherwise modify a contractor’s obligations under the FLSA, SCA, DBA, or any other law. For example, as reflected in 29 CFR 10.26(c), the requirements of E.O. 13658 do not limit or otherwise modify a contractor’s payroll and recordkeeping obligations, if any, under the FLSA, SCA, or DBA, or their implementing regulations. E.O. 13838 and 29 CFR 10.4(g) therefore do not exempt a contractor who is subject to the exemption established by E.O. 13838 and by 29 CFR 10.4(g), from the requirements of the FLSA, SCA, DBA, or any other applicable law.

IV. Administrative Procedure Act

The Department promulgates this final rule without notice or an opportunity for public comment because this action is limited to implementing E.O. 13838 by inserting into the Department’s regulations the identical language 13658 inserted into E.O. 13658. The Administrative Procedure Act (APA) provides that the notice-and-comment procedure does not apply when an agency for good cause finds that it is “impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. 553(b)(3)(B). Notice and comment are “unnecessary,” within the meaning of the APA, when changes to regulations “merely restate” the changes in the enabling authority that they implement. Gray Panthers Advocacy Cnt. v. Sullivan, 936 F.2d 1284, 1291 (D.C. Cir. 1991). In other words, the normal “notice-and-comment procedures” are not required when an agency “reiterates” an existing requirement by “reprinting” that requirement in its own regulations.

Here, the Department for good cause finds that notice and comment are unnecessary because this rule updates the October 7, 2014, regulation to conform with E.O. 13838 by inserting into the regulation the identical language that E.O. 13838 inserted into E.O. 13658. Thus, the rule is merely restating the changes to the enabling authority—E.O. 13658—that these regulations implement. E.O. 13838 requires agencies “to implement [its] exemption and to ensure that all applicable regulations and agency guidance are consistent with [the E.O.],” and the Department lacks the discretion to deviate from this directive. The Department has explained that in this circumstance, it “may not, in response to public comment, change or decline to implement [an] amendment” to an executive order. 68 FR 56392 (Sept. 30, 2003). Indeed, it has promulgated final rules without notice and comment in similar situations. See, e.g., Affirmative Action Obligations of Government Contractors, 68 FR 56392 (Sept. 30, 2003) (add[ing] a a language into regulations). The Department accordingly finds that notice and comment are “unnecessary” under the APA.

Additionally, this rule is effective on the date of publication because the standard 30-day delay does not apply when a rule recognizes an exemption or relieves a restriction. 5 U.S.C. 553(d)(1). This final rule establishes no new burdens on the regulated community; rather it relaxes an existing restriction. The Department has explained that, under the APA, when a rule “relieves
present restrictions, delay in its effective date is excused by 5 U.S.C. 553(d)(1).” 33 FR 8542 (June 11, 1968); see also 45 FR 35325 (May 27, 1980). The Department has followed this interpretation on numerous occasions, having rules become effective upon issuance when they recognized an exemption to a generally applicable duty or relieved a regulated community of a restriction. See, e.g., Cranes and Derricks in Construction, 82 FR 51986 (Nov. 9, 2017); Employment of Homeworkers in Certain Industries, 49 FR 11792 (Mar. 27, 1984); Farm Labor Contractor Registration, 45 FR 25323 (May 27, 1980); Procedures for Consolidation of Existing Exclusively Recognized Units, 40 FR 50714 (Oct. 31, 1975); Federal Extension Service Exemption, 33 FR 8542 (June 11, 1968). Because this rule relieves the regulated community of a compliance duty, a 30-day delay is unnecessary and the rule is effective upon issuance.

In short, the rule promulgated today adds into the Department’s regulations the identical text that E.O. 13838 inserted into E.O. 13658. This action recognizes an exemption to E.O. 13658’s requirements for certain contracts. In this circumstance, issuance of the rule without notice and comment is proper, as is the rule’s effectiveness upon publication.

V. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 et seq., and its attendant regulations, 5 CFR part 1320, require the Department to consider the agency’s need for its information collections and their practical utility, as well as the impact of paperwork and other information collection burdens imposed on the public, and how to minimize those burdens. The PRA typically requires an agency to provide notice and seek public comments on any proposed collection of information contained in a rule. See 44 U.S.C. 3506(c)(2)(B); 5 CFR 1320.8. This rule does not contain a collection of information subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act.

VI. Analysis Conducted in Accordance With E.O. 12866, Regulatory Planning and Review, and E.O. 13563, Improved Regulation and Regulatory Review

A. Introduction

Under E.O. 12866, OMB’s Office of Information and Regulatory Affairs determines whether a regulatory action is significant and, therefore, subject to the requirements of the E.O. and OMB review.3 Section 3(f) of E.O. 12866 defines a “significant regulatory action” as an action that is likely to result in a rule that: (1) Has an annual effect on the economy of $100 million or more, or adversely affects in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as economically significant); (2) creates serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the E.O. Because the annual effect of this rule would be less than $100 million, this rule would not be economically significant under section 3(f) of E.O. 12866.

E.O. 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; that it is tailored to impose the least burden on society, consistent with achieving the regulatory objectives; and that, in choosing among alternative regulatory approaches, the agency has selected the approaches that maximize net benefits. E.O. 13563 recognizes that some benefits are difficult to quantify, including equity, human dignity, fairness, and distributive impacts.

This rule is an E.O. 13771 deregulatory action.

B. Economic Analysis

E.O. 13658 required an increase in the minimum wage to $10.10 for workers on covered Federal contracts where the solicitation for such contracts was issued (or the contract was awarded outside the solicitation process) on or after January 1, 2015. The E.O. applied only to new contracts. Each year, pursuant to E.O. 13658, the Department adjusts this minimum wage using the Consumer Price Index for Urban Wage Earners and Clerical Workers (CPI–W). As of January 2018, the minimum wage for non-tipped covered workers on covered Federal contracts was $10.35.

E.O. 13838, issued on May 25, 2018, exempts from E.O. 13658 contracts with the Federal Government in connection with seasonal recreational services or seasonal recreational equipment rental for the general public on Federal lands. E.O. 13838 directs executive departments and agencies to implement promptly the exemption. This economic analysis attempts to quantify the transfers and costs associated with the exemption from E.O. 13658 for recreational services on Federal lands, and it provides a qualitative discussion of benefits. Under E.O. 13838, exempted contractors no longer have to pay a minimum wage of $10.35; they can instead pay, at least, the higher of either the Federal minimum wage of $7.25 or any applicable state or local minimum wage. Transfers will occur when employers choose to adjust employees’ wages below $10.35.

C. Transfer Calculation

To calculate transfers, the Department first determined the number of potential workers that E.O. 13838 could affect. There is no single source that provides data on how many workers are employed on contracts in connection with seasonal recreational services on Federal lands, so the Department relied on a variety of data sources to estimate the number of affected workers. The Department assumes that most impacted workers will fall under two Standard Occupational Classification (SOC) codes: SOC 39–7010 Tour and Travel Guides, and SOC 39–9032 Recreation Workers. The Department recognizes that impacted workers may be found in additional occupations, but this analysis is limited to these two occupations because the Department lacks more substantive data on other workers. The Department also recognizes that E.O. 13658 and E.O. 13838 do not govern all workers in these two occupations, but limiting the number of impacted workers to Federal contract workers in those occupations will help narrow the analysis to the impacted population.

According to data from the Bureau of Labor Statistics (BLS) Occupational Employment Statistics (OES) program, as of May 2017, the economy had 46,140 workers employed as Tour and Travel Guides and had 352,350 workers employed as Recreation Workers—totaling 398,490 workers employed in those two occupations.4 These two occupations together represent approximately 0.28 percent of employment in the United States.5 To estimate the total number of impacted workers, the Department also

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4 May 2017 employment in all occupations was 142,549,250. BLS OES, https://www.bls.gov/oes/tabs.htm.

5 58 FR 51735 (Sept. 30, 1993).
needed to determine the number of workers carrying out Federal contracts. The Department has previously estimated that annually, 1,727,000 workers carry out Federal contracts in the four categories covered by E.O. 13658. This figure is an approximation only. The Department multiplied 0.28 percent (the occupational share) by the number of workers on covered Federal contracts to estimate the number of Federal-contract workers who are employed in connection with recreational services. The Department thus estimates that there are 4,828 workers (1,727,000 × 0.28%) employed on Federal contracts as outfitters, guides, and other recreational-service workers. Because about 20 percent of Federal contracts are initiated each year and because E.O. 13658 has been in effect for fewer than four years, the Department estimates that 3,862 (4,828 × 80%) workers will be affected by this rule.

This economic analysis attempts to calculate the total potential transfers from employers to employees when employers no longer have to pay the E.O. 13658 minimum wage, which is currently $10.35. The Department assumes that employers with contracts on Federal lands who were paying $10.35 before E.O. 13383 will now choose to pay the Federal minimum wage of $7.25. The Department assumes that employers who pay workers more than the minimum wage of $10.35 will continue paying those wages and therefore will not be affected. The analysis assumes that only those making $10.35 per hour will be affected. Because there is no easily accessible data on the exact wages of seasonal recreational employees on Federal contracts, the Department used the distribution of employment within specific wage ranges from BLS Occupational Employment Statistics to estimate the share of workers earning $10.35 or less. The Department therefore assumes that everyone making $10.35 or less is actually earning the minimum of $10.35. Using a linear approximation of the employment share earning $10.35 within the weighted wage ranges for Tour and Travel Guides and Recreation Workers occupations, the Department estimates that 30.83 percent of workers in the Tour and Travel Guides and Recreation Workers occupations earn $10.35 or less. Applying this share to the previous calculation of workers employed on Federal contracts as outfitters, guides, and other recreational-service workers, the Department estimates that 1,191 of these workers earn $10.35 per hour. The total value of these transfers is estimated to be the difference between $10.35 and the minimum wage for each of these workers. Because data are not available to distinguish these workers by state, the Department calculated the difference between $10.35 and the Federal minimum wage of $7.25. This transfer calculation is therefore likely to be an overestimation because some workers will earn their applicable state minimum wage (which is higher than $7.25) and because, in many other instances, contractors with contracts that are now exempt from E.O. 13658 will choose to pay these workers more than the applicable Federal or state minimum wage (though less than $10.35). Multiplying the $3.10 difference in wages by the 1,191 affected workers for 1,040 hours per year, the Department estimates that total transfers will be $3,839,784 at discount rates of both 3 percent and 7 percent.

D. Costs

The costs associated with this rulemaking are regulatory familiarization costs and any costs that businesses will incur to change their existing payroll systems. Regulatory familiarization costs represent direct costs on businesses associated with reviewing the new regulation. In this rule, regulatory familiarization costs are a function of the number of contractor firms, and only firms that have contracts with the Federal Government in connection with seasonal recreational services will incur costs. For this activity, the Department estimates that contractor firms will spend 15 minutes to determine whether the exemption applies to them, to evaluate and adjust their pay rates, and to modify their payroll systems. For familiarization cost analysis, the Department assumes that a

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9 For purposes of this analysis, the Department assumes that the occupational distribution of workers on Federal contracts is the same as in the overall economy. In reality, the occupational distribution may differ, so this number may be imprecise.

10 Full-time, year-round workers usually work around 2,080 hours. Because most affected workers are seasonal, the Department used half of this number as an estimate for usual hours-worked in a year.

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11 Compensation/benefits specialist ensures company compliance with Federal and state laws, including reporting requirements; evaluates, improves, and communicates methods and techniques for selecting, promoting, compensating, evaluating, and training workers.

12 This estimate includes firms registered in the General Services Administration’s (GSA) System for Award Management (SAM) and from additional data sources. For a full discussion of this methodology and estimate, see https://www.federalregister.gov/documents/2016/09/30/2016-22964/establishing-paid-sick-leave-for-federal-contractors.
F. Summary of Transfers and Costs

Table 1 provides a summary of the quantified transfers and costs for this rule.

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<td>10-Year Annualized Transfers</td>
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</table>

G. Regulatory Flexibility Analysis

In 2014, the Small Business Association’s Office of Advocacy provided comments on the regulations implementing E.O. 13658 (Establishing a Minimum Wage for Federal Contractors). The comment letter urged the Department to adopt a regulatory alternative that exempts recreational companies and provides regulatory cost savings for small businesses. In 2018, small business stakeholders also recommended this rule for regulatory reform under E.O. 13771. Per the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. (as amended), the Department examined the regulatory requirements of the rule to determine whether they would have a significant economic impact on a substantial number of small entities. As indicated in Section B, Economic Analysis, the annualized burden is estimated to be $2,236 at a discount rate of 7 percent; therefore, the annualized cost per firm is estimated to be $1.63 (= $2,236 + 1,368 firms). See Table 2.

<table>
<thead>
<tr>
<th>TABLE 2—ANNUAL COST PER FIRM—Continued</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated number of firms .......... 1,368</td>
</tr>
<tr>
<td>Compensation, Benefits, and Job Analysis Specialists fully loaded hourly compensation ................. <strong>$49.13</strong></td>
</tr>
<tr>
<td>Time to review rule and make payroll adjustments .............. <em>15 minutes</em></td>
</tr>
<tr>
<td>Total cost .................................. $16,804</td>
</tr>
<tr>
<td>Annualized cost per firm ............... $2,236</td>
</tr>
<tr>
<td>Annualized with 7% Discounting ........ $1.63</td>
</tr>
</tbody>
</table>

*Minutes.

Table 3 provides the annualized cost per firm as a percentage of revenue by firm size in the arts, entertainment, and recreation industry. As the table shows, the annualized burden as a percentage of the smallest employer’s revenue would be far less than 1 percent. Accordingly, the Department certifies that the rule would not have a significant economic impact on a substantial number of small entities.

<table>
<thead>
<tr>
<th>TABLE 3—ANNUAL COST PER FIRM IN THE ARTS, ENTERTAINMENT, AND RECREATION INDUSTRY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of firms</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue below $100,000 ........................................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $100,000 to $499,999 ...............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $500,000 to $999,999 ...............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $1,000,000 to $2,499,999 .............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $2,500,000 to $4,999,999 ..............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $5,000,000 to $7,499,999 ..............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $7,500,000 to $9,999,999 ..............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $10,000,000 to $14,999,999 ............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $15,000,000 to $19,999,999 .............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $20,000,000 to $24,999,999 .............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $25,000,000 to $29,999,999 .............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $30,000,000 to $34,999,999 .............................</td>
</tr>
<tr>
<td>Firms with sales/receipts/revenue of $35,000,000 to $39,999,999 .............................</td>
</tr>
</tbody>
</table>

H. Unfunded Mandates Reform Act

This rule has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA).
I. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, August 10, 1999). This rule does not have federalism implications as outlined in E.O. 13132. The rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

J. Executive Order 13175, Indian Tribal Governments

The Department has reviewed this rule under the terms of Executive Order 13175 (65 FR 67249, November 6, 2000) and determined it does not have “tribal implications.” The rule does not have “substantial direct effects 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.” As a result, no Tribal summary impact statement has been prepared.

VII. Regulatory Revision

For the reasons set forth in the preamble, the Department of Labor amends part 10 of title 29 of the Code of Federal Regulations as follows:

PART 10—ESTABLISHING A MINIMUM WAGE FOR CONTRACTORS

1. The authority citation for part 10 is revised to read as follows:


2. In §10.4, add paragraph (g) to read as follows:

§10.4 Exclusions.

* * * * *

(g) Contracts in connection with seasonal recreational services and seasonal recreational equipment rental offered for public use on Federal lands. This part shall not apply to contracts or contract-like instruments entered into with the Federal Government in connection with seasonal recreational services or seasonal recreational equipment rental for the general public on Federal lands, but this exemption shall not apply to lodging and food services associated with seasonal recreational services. Seasonal recreational services include river running, hunting, fishing, horseback riding, camping, mountaineering activities, recreational ski services, and youth camps.

Signed in Washington, DC, this 18th day of September.

Bryan L. Jarrett,
Acting Administrator, Wage and Hour Division.

[FR Doc. 2018–20757 Filed 9–25–18; 8:45 am]
BILLING CODE 4510–27–P

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 34

RIN 1290–AA32

Rescission of Regulations Implementing the Nondiscrimination and Equal Opportunity Provisions of the Job Training Partnership Act of 1982

AGENCY: Office of the Assistant Secretary for Administration and Management, Department of Labor.

ACTION: Direct final rule.

SUMMARY: The U.S. Department of Labor takes this action to remove regulations for an inoperative program but continues to require non-discrimination and equal-employment opportunity under its programs. The Department is undergoing a process of identifying identify regulations that are “outdated” and “unnecessary.” The regulations being rescinded by this rule are “outdated” because they administer a program that no longer exists. And they are “unnecessary” because they currently serve no purpose, as their existence or non-existence has no impact on the Department’s enforcement of non-discrimination standards under its existing programs. In particular, the Department is rescinding its regulations implementing Section 167 of the Job Training Partnership Act of 1982, as amended (JTPA). Section 167 contained the nondiscrimination and equal-opportunity provisions of the JTPA. In 1998, Congress passed the Workforce Investment Act (WIA), which repealed the JTPA and required the Secretary of Labor to transition any authority under the JTPA to the system that WIA created. WIA, in turn, was subsequently altered by the Workforce Innovation and Opportunity Act (WIOA). In sum, this rule removes regulations for an inoperative program, but has no impact on existing non-discrimination rules.

DATES: This direct final rule is effective on November 26, 2018, unless the Department receives a significant adverse comment to this direct final rule or the companion proposed rule by October 26, 2018, on any unintended changes this action makes in the nondiscrimination and equal opportunity obligations the Department enforces. If timely, significant adverse comment is received, the Department will publish a notification of withdrawal of the direct final rule in the Federal Register before the effective date. Such notification may withdraw the direct final rule in whole or in part.

ADDRESSES: Comments may be submitted, identified by Regulatory Information Number (RIN) 1290–AA32, by any one of the following methods:


• Fax: (202) 693–6505 (for comments of six pages or less).

• Mail or Hand Delivery/Courier: Naomi Barry-Perez, Director, Civil Rights Center (CRC), U.S. Department of Labor, 200 Constitution Avenue NW, Room N–4123, Washington, DC 20210.

• Email: CRC–WIOA@dol.gov.

Please submit your comment by only one method. Receipt of comments will not be acknowledged; however, the Department will post all comments received on http://www.regulations.gov without making any change to the comments, including any personal information provided. The http://www.regulations.gov website is the Federal e-rulemaking portal, and all comments posted there are available and accessible to the public.

The Department cautions commenters not to include personal information, such as Social Security Numbers, personal addresses, telephone numbers and email addresses, in comments, as such submitted information will become viewable by the public via http://www.regulations.gov. It is the responsibility of the commenter to safeguard personal information. Comments submitted through http://www.regulations.gov will not include the commenter’s email address unless the commenter chooses to include that information as part of a comment.

Postal delivery in Washington, DC, may be delayed due to security concerns. Therefore, the Department encourages the public to submit comments via the website indicated above.

The Department will also make all the comments it receives available for public inspection during normal business hours at the Civil Rights Center at the above address and email address. The Department will provide you with
appropriate aids such as readers or print magnifiers. The Department will make copies of this rule available, upon request, in large print and as an electronic file on computer disk. The Department will consider providing the rule in other formats upon request. To schedule an appointment to review the comments and/or obtain the rule in an alternate format, contact CRC at (202) 693–6500 (VOICE) or (800) 877–8339 (TTY).

FOR FURTHER INFORMATION CONTACT:
Naomi Barry-Perez, Director, Civil Rights Center, U.S. Department of Labor, 200 Constitution Avenue NW, Room N– 4123, Washington, DC 20210, telephone (202) 693–6500 (VOICE) or (800) 877–8339 (Federal Relay Service—for TTY), or by email at CRC–WIOA@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under the JTPA, the Department of Labor provided financial assistance to certain recipients for the purpose of establishing programs to meet the job training needs of youth and adults facing serious barriers to employment. Section 167 of the JTPA contained nondiscrimination and equal opportunity provisions that prohibited discrimination on the grounds of race, color, religion, sex, national origin, age, disability, political affiliation or belief, and for beneficiaries only, citizenship status or participation in a JTPA-funded program or activity. As amended by the Job Training Reform Amendments of 1992, the JTPA provided that final regulations implementing Section 167 be issued within 90 days of the enactment date of the Job Training Reform Amendments of 1992. On January 15, 1993, the Department issued the implementing regulations at 29 CFR part 34 for the nondiscrimination and equal opportunity provisions of the JTPA. The rule applied to recipients of Federal financial assistance under the JTPA. The rule imposed general nondiscrimination and equal opportunity requirements, as well as certain affirmative obligations, such as data collection and recordkeeping requirements.

The JTPA was repealed by the Workforce Investment Act of 1998 (WIA). The Department’s regulations implementing WIA provided for the phased transition of the JTPA programs to WIA, to be fully completed by July 1, 2000. Section 188 of WIA contained substantially similar nondiscrimination and equal opportunity requirements as those contained in the JTPA. The Department issued regulations implementing WIA Section 188 at 29 CFR part 37 on November 12, 1999. WIA in turn was superseded by the Workforce Innovation and Opportunity Act (WIOA) in 2014. Section 188 of WIOA contains the same nondiscrimination and equal opportunity provisions as those in WIA. The Department issued final regulations implementing WIOA Section 188 at 29 CFR part 38 on December 2, 2016.

II. Purpose of the Regulatory Action

The purpose of this action is to rescind the regulations implementing the nondiscrimination and equal opportunity provisions of the JTPA. All funding under the JTPA, together with the obligation to comply with the nondiscrimination and equal opportunity requirements of Section 167, has now expired. The Section 167 regulations have been superseded by those implementing Section 188 of first WIA, then WIOA. The regulations at 29 CFR part 34 governed a program that has not been in operation for more than a decade and so were outdated and unnecessary. Therefore, the rescission of the regulations is ministerial in nature.

III. Statement of Legal Authority

Statutory Authority

The Department effects this rescission consistent with the repeal of the JTPA in Section 199(b)(2) of the Workforce Investment Act of 1998, Public Law 105–220.

Departmental Authorization

CRC issued the regulations implementing the nondiscrimination and equal opportunity obligations of the JTPA pursuant to Secretary’s Order 2–81, 50 FR 28853 (July 16, 1985), which authorized the Assistant Secretary for Administration and Management (OASAM), working through the Director, Office of Civil Rights (OCR), to establish and formulate all policies, standards, and procedures, as well as to issue rules and regulations, governing the civil rights enforcement programs under grant-related nondiscrimination statutes. Secretary’s Order 2–85 similarly delegated to OASAM, working through the Director, OCR, now CRC, exclusive authority for the implementation and enforcement of the nondiscrimination and equal opportunity provisions of the JTPA. Secretary’s Orders 2–81 and 2–85 were canceled following the repeal of the JTPA. Secretary’s Order 04–2000, 65 FR 69184 (Nov. 15, 2000), re-delegated the relevant responsibilities to CRC. The delegation in Secretary’s Order 04–2000 covers CRC’s rescission of the regulations implementing the nondiscrimination and equal opportunity provisions of the JTPA.

IV. Rulemaking Analyses and Notices

A. Administrative Procedure Act and Direct Final Rulemaking

Direct final rulemaking in this instance is appropriate because the action is solely ministerial in nature, the underlying statute (Section 167 of the JTPA) has been superseded by the requirements of Section 188 of WIA and WIOA, and all funding under the JTPA has expired. Direct final rulemaking is used when a rule is noncontroversial and is expected to elicit no adverse comment. Here, direct final rulemaking is appropriate because the rule does nothing more than remove regulations for a program that is no longer operative. Under this circumstance, the use of direct final rulemaking satisfies APA requirements.

The Department is publishing concurrently with this direct final rule an identical notice of proposed rulemaking elsewhere in this issue of the Federal Register. The companion proposed rule provides the procedural framework to finalize the rule in the event that any significant adverse comment is received. The comment period for this direct final rule runs concurrently with the comment period for the proposed rule. Any comments received in response to this direct final rule will also be considered as comments regarding the companion proposed rule.

If any significant adverse comments are received during the comment period, the Department will withdraw the direct final rule and proceed in developing a final rule using the usual notice-and-comment procedure. If no significant adverse comment is received during the comment period, the Department will publish a document withdrawing the proposed rule.

B. Executive Orders 12866, 13563, and 13771

This rule is not a “significant regulatory action” within the meaning of Executive Order 12866 and the principles reaffirmed in Executive Order 13563. In addition, this rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

C. Paperwork Reduction Act

This regulatory action will not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.
D. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have federalism implications. This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

E. Unfunded Mandates Reform Act of 1995

This rule does not contain a Federal mandate that will result in the expenditure by State, local, and tribal governments, in aggregate, or by the private sector of $100 million or more in any one year.

F. Assessment of Federal Regulations and Policies on Families

This rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act 1999, 5 U.S.C. 601 note.

G. Regulatory Flexibility Act of 1980

Pursuant to Section 605(b) of the Regulatory Flexibility Act, CRC certifies that this rule will not have a significant economic impact on a substantial number of small entities. See 5 U.S.C. 605(b). As explained above, this rule is ministerial in nature and does not impose any additional regulatory burdens.

H. Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

I. Executive Order 13175 (Indian Tribal Governments)

This rule does not have tribal implications under Executive Order 13175 that would require a tribal summary impact statement. The rule would not have substantial direct effects 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.

J. Executive Order 12630 (Government Actions and Interference With Constitutionally Protected Property Rights)

This rule is not subject to Executive Order 12630 because it does not involve implementation of a policy that has takings implications or that could impose limitations on private property use.

K. Executive Order 12988 (Civil Justice Reform)

The rule was drafted and reviewed in accordance with Executive Order 12988 and will not unduly burden the Federal court system. The rule was: (1) Reviewed to eliminate drafting errors and ambiguities; (2) written to minimize litigation; and (3) written to provide a clear legal standard for affected conduct and to promote burden reduction.

List of Subjects in 29 CFR Part 34

Implementation of the Nondiscrimination and Equal Opportunity Requirements of the Job Training Partnership Act of 1982, as Amended (JTPA).

For the reasons set forth in the preamble, the Department rescinds 29 CFR part 34 in its entirety as follows:

PART 34—[REMOVED AND RESERVED]

1. Remove and reserve part 34, consisting of §§ 34.1 through 34.53.

Signed at Washington DC, on September 13, 2018.

Bryan Slater,
Assistant Secretary, Office of the Assistant Secretary for Administration and Management, Department of Labor.

[FR Doc. 2018–20411 Filed 9–25–18; 8:45 am]
BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

[Docket No. USCG–2018–0245]

RIN 1625–AC45

Ballast Water Management—Annual Reporting Requirement

Correction

In rule document 2018–20374, appearing on pages 47284 through 47293, in the issue of Wednesday, September 19, 2018, make the following correction:

On page 47291, in Table 5, under the table heading, in the second column, the column heading titled “Current COI respondents (B)” is corrected to read “COI burden hours (B)”.

BILLING CODE 1301–00–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 6

[FRL–9984–09–OP]

Amendment of the NEPA Official Under Procedures for Implementing the National Environmental Policy Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule amends the Environmental Protection Agency’s (“EPA”) responsibility of the NEPA Official under its existing regulations for “Implementing the National Environmental Policy Act and Assessing the Environmental Effects Abroad of EPA Actions.” This amendment is a result of an agency reorganization that only impacts a title change of the designated NEPA Official under the existing regulations. This amendment is procedural in nature and none of these changes are intended to substantively alter the Agency’s compliance with the National Environmental Policy Act for the EPA’s actions.

DATES: This final rule is effective on September 26, 2018.

FOR FURTHER INFORMATION CONTACT: Jessica Trice, Office of Federal Activities, NEPA Compliance Division (MC 2252A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 5646646; email address: trice.jessica@epa.gov.

SUPPLEMENTARY INFORMATION: This is organized according to the following outline:

I. General Information
   A. Why is the EPA issuing this rule in final form without first issuing a proposal?
   B. Does this action apply to me?
   C. Statutory Authority
   D. Background
II. EPA’s Final Action
III. Statutory and Executive Order Reviews
I. General Information

A. Why is the EPA issuing this rule in final form without first issuing a proposal?

This final rule is limited to a procedural change in title of the designated NEPA Official under existing regulations as a result of an agency reorganization. Under the Administrative Procedure Act, an agency may issue “rules of agency organization, procedure, or practice” without first proposing such rules for public comment, 5 U.S.C. 553(b). Accordingly, public comment is not required.

B. Does this action apply to me?

This action affects only two agency officials associated with responsibilities for EPA’s NEPA compliance due to the reorganization of the Office of Federal Activities within the EPA. The agency officials affected include the Assistant Administrator for the Office of Enforcement and Compliance Assurance, and the Associate Administrator for the Office of Policy.

C. Statutory Authority

The National Environmental Policy Act (NEPA) establishes the federal government’s national policy for protection of the environment (42 U.S.C. 4321–75). The Council on Environmental Quality’s (CEQ) regulations at 40 CFR parts 1500 through 1508 establish procedures implementing this national policy. The CEQ’s regulations (40 CFR 1505.1) require federal agencies to adopt and, as needed, revise their own NEPA implementing procedures to supplement the CEQ regulations and to ensure their decision-making processes are consistent with NEPA. The EPA is taking this action—changing the title of the designated NEPA Official under existing regulations as a result of an agency reorganization—under the authority of 5 U.S.C. 301.

D. Background

The EPA established regulations for implementing NEPA and Executive Order 12114, “Enforcement Effects of Major Federal Actions,” titled “Procedures for Implementing the National Environmental Policy Act and Assessing the Environmental Effects Abroad of EPA Actions” (40 CFR part 6). Title 40 CFR 6.102 of the Agency’s current regulations provide additional definitions applicable to 40 CFR part 6, subparts A through C, including the designation of the Assistant Administrator for Enforcement and Compliance Assurance as the EPA’s "NEPA Official.” The NEPA Official is responsible for the EPA’s compliance with NEPA. The Office of Federal Activities, historically within the Office of Enforcement and Compliance Assurance, provides support and guidance to the designated NEPA Official regarding the EPA’s compliance with NEPA. Effective on April 29, 2018, an agency reorganization moved the Office of Federal Activities from the Office of Enforcement and Compliance Assurance to the Office of the Administrator. The action is procedural in nature and none of these changes are intended to substantively alter the Agency’s compliance with NEPA for the EPA’s actions.

II. EPA’s Final Action

As a result of the reorganization, this final Agency rule implements a procedural change that amends the title of the designated NEPA Official under existing regulations from the Assistant Administrator for Enforcement and Compliance Assurance to the Associate Administrator for the Office of Policy.

III. Statutory and Executive Order Reviews

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

This action is exempt from review by the Office of Management and Budget (OMB) because it is limited to agency organization, management, or personnel matters.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act

This action does not impose an information collection burden under the PRA.

D. Regulatory Flexibility Act

This action is not subject to the RFA. The RFA applies only to rules subject to notice and comment rulemaking requirements under the Administrative Procedures Act (APA), 5 U.S.C. 553, or any other statute. This rule pertains to agency management or personnel, which the APA expressly exempts from notice and comment rulemaking requirements under 5 U.S.C. 553(a)(2).

E. Unfunded Mandates Reform Act

This action does not contain any unfunded mandate as described in the Unfunded Mandates Reform Act, 2 U.S.C. 1531–38, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effect on the States, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. This action implements a procedural change to the title of the designated NEPA Official under existing regulations. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health or safety risk.

I. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

The action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994).
This action implements a procedural change to the title of the designated NEPA Official under existing regulations.

**L. Congressional Review Act**

This rule is exempt from the CRA because it is a rule relating to agency management or personnel.

**List of Subjects in 40 CFR Part 6**

Environmental protection, Environmental impact statements, Foreign relations, Grant programs, Reporting and recordkeeping requirements, Waste treatment and disposal.

Dated: September 13, 2018.

Andrew R. Wheeler,
Acting Administrator.

For the reasons set forth in the preamble, the Environmental Protection Agency amends 40 CFR part 6 as follows:

**PART 6—PROcedures for Implementing the National Environmental Policy Act and Assessing the Environmental Effects Aboard of EPA Actions**

1. The authority citation for part 6 is revised to read as follows: Authority: 42 U.S.C. 4321 et seq.; also 40 CFR parts 1500 through 1508, unless otherwise noted.

2. Section 6.102 is amended by revising paragraph (b)(8) to read as follows:

§ 6.102 Definitions.

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

(8) NEPA Official is the Associate Administrator of the Office of Policy, who is responsible for EPA’s NEPA compliance.

* * * * * * *

[FR Doc. 2018–20856 Filed 9–25–18; 8:45 am]

**BILLING CODE 6560–50–P**

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**ENVIRONMENTAL PROTECTION AGENCY**

40 CFR Parts 9 and 721


RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances; Withdrawal

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

**ACTION:** Withdrawal of direct final rule.

**SUMMARY:** EPA is withdrawing significant new use rules (SNURs) promulgated under the Toxic Substances Control Act (TSCA) for 145 chemical substances, which were the subjects of premanufacture notices (PMNs). EPA published these SNURs using direct final rulemaking procedures, which requires EPA to take certain actions if an adverse comment is received. EPA received adverse comments regarding the SNURs identified in this document. Therefore, the Agency is withdrawing the direct final rule SNURs identified in this document, as required under the direct final rulemaking procedures.

**DATES:** The direct final rule published at 83 FR 37702 on August 1, 2018, is withdrawn effective September 26, 2018.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2017–0366, is available at http://www.regulations.gov or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

**FOR FURTHER INFORMATION CONTACT:**

For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABV1-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: TSCA-Hotline@epa.gov.

**SUPPLEMENTARY INFORMATION:**

### I. Does this action apply to me?

The list of potentially affected entities is provided in the Federal Register of August 1, 2018 (83 FR 37702) (FRL–9970–23). If you have questions regarding the applicability of this action to a particular entity, consult the technical person listed under FOR FURTHER INFORMATION CONTACT.

### II. What direct final SNURs are being withdrawn?

In the Federal Register of August 1, 2018 (83 FR 37702), EPA issued direct final SNURs for all 145 chemical substances that are identified in this document. Because the Agency received adverse comments that relate to each of the 145 chemical substances, EPA is withdrawing the direct final SNURS issued for these 145 chemical substances. In addition to the Direct Final SNURs, elsewhere in the same issue of the Federal Register of August 1, 2018, EPA proposed SNURS covering these 145 chemical substances (83 FR 37455) (FRL–9981–16). EPA will address all adverse public comments in a subsequent final rule, based on the proposed rule.

### III. Good Cause Finding

EPA determined that this document is not subject to the 30-day delay of effective date generally required by the Administrative Procedure Act (APA) (5 U.S.C. 553(d)) because of the time limitations for publication in the Federal Register. This document must publish on or before the effective date of the direct final rule containing the direct final SNURs being withdrawn.

### IV. Statutory and Executive Order Reviews

This action withdraws regulatory requirements that have not gone into effect and which contain no new or amended requirements. As such, the Agency has determined that this action will not have any adverse impacts, economic or otherwise. The statutory and Executive Order review requirements applicable to the direct final rule were discussed in the August 1, 2018 Federal Register. Those review requirements do not apply to this action because it is a withdrawal and does not contain any new or amended requirements.

### V. Congressional Review Act (CRA)

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). Section 808 of the CRA allows the issuing agency to make a rule effective sooner than otherwise provided by CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary, or contrary to the public interest. As
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52


Air Plan Approval; Tennessee: Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a portion of a revision to the Chattanooga-Hamilton County portion of the Tennessee State Implementation Plan (SIP) submitted by the State of Tennessee through the Tennessee Department of Environment and Conservation (TDEC) on behalf of the Chattanooga-Hamilton County Air Pollution Control Bureau (Chattanooga-Hamilton County) on June 25, 2008. The revision amends the definition of “volatile organic compounds” (VOC) to be consistent with state and Federal regulations. The portion of the SIP revision that EPA is approving is consistent with the requirements of the Clean Air Act (CAA or Act). EPA will act on the other portions of the June 25, 2008, submittal in a separate action.

DATES: This rule will be effective October 26, 2018.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2017–0395. All documents in the docket are listed on the www.regulations.gov website. Although listed in the index, some information is not publicly available, i.e., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the FOR FURTHER INFORMATION CONTACT section to schedule your inspection. The Regional Office’s official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Tiereny Bell, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. Ms. Bell can be reached by phone at (404) 562–9088 or via electronic mail at bell.tiereny@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On March 13, 2018 (83 FR 10813), EPA proposed to approve into the Tennessee SIP the portion of the revisions to the Chattanooga-Hamilton County air quality rules in Chapter 4 of Part II, Section 4–2, submitted by TDEC on behalf of Chattanooga-Hamilton County on June 25, 2008. The definition of “Volatile Organic Compounds” in Chapter 4 of Part II, Section 4–2, “Definitions” is amended to be consistent with the Federal definition of VOC at 40 CFR 51.100(s). In summary, the amendments add several compounds to the list of negligibly reactive compounds, make minor changes to paragraph 3 (related to preconditions to excluding compounds as VOCs), and adds paragraph 4 (related to test methods used for purposes of enforcement) and paragraph 5 (related to recordkeeping and reporting requirements for t-butyl acetate). The details of the Tennessee submissions and the rationale for EPA’s action are explained in the proposed rulemaking. Comments on the proposed rulemaking were due on or before April 13, 2018. EPA did not receive any adverse comments on the proposed action.

II. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Chattanooga-Hamilton County’s air quality rules in Chapter 4 of Part II, Section 4–2, “Definitions” effective June 11, 2008, to be consistent with the definition of VOC at 51.100. EPA has made, and will continue to make, these materials generally available through www.regulations.gov and at the EPA Region 4 Office (please contact the person identified in the FOR FURTHER INFORMATION CONTACT section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally-enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA’s approval, and will be incorporated by reference in the next update to the SIP compilation.

III. Final Action

EPA is taking final action to approve a portion of a revision to the Chattanooga-Hamilton County portion of the Tennessee SIP which amends the definition of “Volatile Organic Compounds” in the Chattanooga Code, Chapter 4 of Part II, Section 4–2. This SIP revision also amends paragraph 3 and adds paragraphs 4 and 5 to the Chattanooga Code, Chapter 4 of Part II, Section 4–2 definition of VOC. EPA has evaluated the relevant portions of Tennessee’s June 25, 2008, SIP revision and has determined that it meets the applicable requirements of the CAA and EPA regulations.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. See 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA’s role is to approve state choices, provided that they meet the criteria of

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3 In the proposed rule at 83 FR 10814 (March 13, 2018), EPA inadvertently noted the “Definitions” state effective date as August 16, 1995. The correct state effective date, as reflected in this final rule, is June 11, 2008.

4 62 FR 27968 (May 22, 1997).
the CAA. This action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted 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);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 26, 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 13, 2018.

Onis "Trey" Glenn, III,
Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

§ 52.2220 Identification of plan.

(c) * * * * *

Table 4—EPA Approved Chattanooga Regulations

<table>
<thead>
<tr>
<th>State section</th>
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<th>Adoption date</th>
<th>EPA approval date</th>
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<td>Definitions</td>
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<td>9/26/2018, [Insert citation of publication]</td>
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[FR Doc. 2018–20860 Filed 9–25–18; 8:45 am]
ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

2-Propenoic Acid, 2-Methyl-, Polymer With Butyl 2-Methyl-2-Propenoate, Butyl 2-Propenoate, N-(1,1-Dimethyl-3-Oxobutyl)-2-Propenamide, Ethenylbenzene, 2-Ethylhexyl 2-Propenoate and Methyl 2-Methyl-2-Propenoate; Tolerance Exemption

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?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&rgid=50:48549&SID=5c59b302a1c65ef169d8a2805549035f

C. Can I file an objection or hearing request?

Under FFDDCA section 408(g), 21 U.S.C. 346a(d)(3), announcing the receipt of a pesticide petition (PP IN–11150) filed by Spring Trading Company on behalf of BASF Corporation, 100 Park Avenue, Florham Park, New Jersey 07932. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate on food or feed commodities.

DATES: This regulation establishes an exemption for residues of 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate; when used as an inert ingredient in a pesticide chemical formulation. Spring Trading Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate when used as an inert ingredient in a pesticide chemical formulation.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUPPLEMENTARY INFORMATION:

II. Background and Statutory Findings


Section 408(c)(2)(A)(i) of FFDDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDDCA 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.\textsuperscript{12} This includes exposure through drinking water and use 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 an exemption from the requirement of 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…” and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from 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(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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 the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250. Based on its conformance to the criteria given in 40 CFR 723.250(b) and the meeting of the following criteria that are used to identify low-risk polymers:

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.
2. The polymer does contain as an integral part of its composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.
3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).
4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.
5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.
6. The polymer is a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.
7. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF\textsubscript{x}, or longer chain length as listed in 40 CFR 723.250(d)(6).
8. Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).
9. The polymer’s number average MW of 7,300 is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Thus, 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate may be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-diary exposure was possible. The number average MW of 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate is 7,300 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-diary exposure was possible. The number average MW of 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate is 7,300 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate is 7,300 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. 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 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate to share a common mechanism of toxicity with any other substances, and 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has
assumed that 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate 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.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold 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 data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate. EPA finds that 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 not established a MRL for 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate.

IX. Conclusion

Accordingly, EPA finds that 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 not established a MRL for 2-propenoic acid, 2-methyl-, polymer with butyl 2-methyl-2-propenoate, butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene, 2-ethylhexyl 2-propenoate and methyl 2-methyl-2-propenoate.

X. Statutory and Executive Order Reviews

This action establishes 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 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). 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).

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).

XI. 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.
**ENVIRONMENTAL PROTECTION AGENCY**

40 CFR Part 180  

**Maltodextrin-Vinyl Pyrrolidinone Copolymer; Exemption From the Requirement of a Tolerance**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement for residues of maltodextrin-vinyl pyrrolidinone copolymer (CAS Reg. No. 132383–56–2) when used as an inert ingredient in a pesticide chemical formulation. Akzo Nobel Surface Chemistry, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of maltodextrin-vinyl pyrrolidinone copolymer on food or feed commodities.

**DATES:** This regulation is effective September 26, 2018. Objections and requests for hearings must be received on or before November 26, 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–2018–0289, 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 Bldg., 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: RDRFRNotices@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 202).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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


**C. Can I file an objection or hearing request?**

Under FFDCA section 408(g), 21 U.S.C. 346a, anyone 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–2018–0289 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 November 26, 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–2018–0289, by one of the following methods:

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 docket generally, is available at http://www.epa.gov/dockets.

II. Background and Statutory Findings

In the Federal Register of August 14, 2018 (83 FR 40272) [FRL–9981–10], EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN–11127) filed by Akzo Nobel Surface Chemistry, LLC, 203 Dogwood Trail, Magnolia, TX 77354. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of maltodextrin-vinyl pyrrolidinone copolymer (CAS Reg. No. 1323833–56–2). That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner’s request. The Agency did not receive any comments.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” 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 use 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 an exemption from the requirement of 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.” and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown 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(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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 the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250. Based on this definition, maltodextrin-vinyl pyrrolidinone copolymer meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to maltodextrin-vinyl pyrrolidinone copolymer.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that maltodextrin-vinyl pyrrolidinone copolymer could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The minimum number average MW of maltodextrin-vinyl pyrrolidinone copolymer is 21,000 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since maltodextrin-vinyl pyrrolidinone copolymer conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. 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 maltodextrin-vinyl pyrrolidinone copolymer to share a common mechanism of toxicity with any other substances, and maltodextrin-
vi nyl pyrrolidinone copolymer does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that maltodextrin-vinyl pyrrolidinone copolymer 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.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold 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 data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of maltodextrin-vinyl pyrrolidinone copolymer, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of maltodextrin-vinyl pyrrolidinone copolymer.

VIII. Other Considerations

A. 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.

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 FDCA 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 not established a MRL for maltodextrin-vinyl pyrrolidinone copolymer.

IX. Conclusion

Accordingly, EPA finds that exempting residues of maltodextrin-vinyl pyrrolidinone copolymer from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This action establishes 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 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). 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 FFDCA 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(b)(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).

XI. 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 § 180.960, add alphabetically the polymer “Maltodextrin-vinyl pyrrolidinone copolymer, minimum number average molecular weight (in amu), 21,000” to the table to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *
SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methylethenyl) benzene, ammonium salt; Tolerance Exemption. This regulation eliminates the exemption from the requirement of a tolerance for residues of 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methylethenyl) benzene, ammonium salt; Tolerance Exemption.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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. 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–2018–0264.

II. Background and Statutory Findings

In the Federal Register of June 14, 2018 (83 FR 27743) (FRL–9978–41), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a(d)(3), announcing the receipt of a pesticide petition (PP IN–11149) filed by Spring Trading Company on behalf of BASF Corporation, 100 Park Avenue, Florham Park, New Jersey 07932. The petition requested that 40 CFR 346a(d)(3), announcing the receipt of a pesticide petition (PP IN–11149) filed by Spring Trading Company on behalf of BASF Corporation, 100 Park Avenue, Florham Park, New Jersey 07932. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-propenoic acid, polymer with butyl 2-propenoate,
ethenylbenzene and (1-methyl)ethenyl benzene, ammonium salt; CAS Reg. No. 360564-31-4. That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner’s request. The Agency did not receive any comments.

Section 408(c)(2)(A)(ii) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” 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 use 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 an exemption from the requirement of 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 . . .” and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown 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(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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 the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d).

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methyl)ethenyl benzene, ammonium salt could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methyl)ethenyl benzene, ammonium salt is 2,300 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methyl)ethenyl benzene, ammonium salt conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. 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 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methyl)ethenyl benzene, ammonium salt to share a common mechanism of toxicity with any other substances, and 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methyl)ethenyl benzene, ammonium salt does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methyl)ethenyl benzene, ammonium salt 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.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold 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 data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methylene) benzene, ammonium salt, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methylene) benzene, ammonium salt.

VIII. Other Considerations

A. 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.

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 FFDDCA 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 agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methylene) benzene, ammonium salt.

IX. Conclusion

Accompanying the EPA finds that exempting residues of 2-propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methylene) benzene, ammonium salt from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDDCA 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). 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 FFDDCA 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 FFDDCA section 408(b)(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).

XI. 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 § 180.960, alphabetically add the polymer “2-Propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methylene) benzene, ammonium salt, minimum number average molecular weight (in amu), 2,300” to the table to read as follows:
§ 180.960 Polymers; exemptions from the requirement of a tolerance.

Polymer | CAS No.
--- | ---
2-Propenoic acid, polymer with butyl 2-propenoate, ethenylbenzene and (1-methylethenyl) benzene, ammonium salt, minimum number average molecular weight (in amu), 2,300 | 360564–31–4

Background

The Head Start Program Performance Standards (81 FR 61294) define standards grantees and delegate agencies must implement to operate high quality Head Start or Early Head Start programs. As part of our effort to prioritize child safety, we strengthened our criminal background check procedures at 45 CFR 1302.90(b) in the final rule to reflect changes in the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, and to complement background check requirements in the Child Care and Development Block Grant (CCDBG) Act of 2014, Public Law 113–186.

In addition to more comprehensive background check standards, we aim to strengthen partnerships between states and Head Start programs. At 45 CFR 1302.53(b) in the final rule, we require Head Start programs to actively promote coordinated early childhood systems, including those in their state. As part of these requirements, most Head Start programs must participate in QRIS, if they meet certain conditions.

Currently, Head Start programs must comply with background check requirements and participate in their states’ QRIS, by September 30, 2018. We have already delayed the date for programs to comply with background check requirements in the final rule to align with the background check requirement deadline in the Child Care Development Block Grant Act of 2014, Public Law 113–186, through a document published in the Federal Register (82 FR 45205) on September 28, 2017. In the same Federal Register document, we extended the date for programs to participate in QRIS.

Through conversations with programs and states, we are concerned programs are still not able to fully implement either background check or QRIS requirements by September 30, 2018, without assuming unintended regulatory and administrative burden.

Background Checks Procedures in the Final Rule

Generally, 45 CFR 1302.90(b)(1) requires that before a person is hired, programs must conduct a sex offender registry check and obtain either a state or tribal criminal history records, including fingerprint checks, or a Federal Bureau of Investigation (FBI) criminal history records, including fingerprint checks.

In 45 CFR 1302.90(b)(2), (4), and (5), we afford programs 90 days to obtain whichever check they could not obtain before the person was hired, as well as child abuse and neglect state registry check, if available. However, programs must ensure newly hired employees do not have unsupervised access to children until their background check process is complete. A complete background check process consists of a sex offender registry check, state or tribal history records, including fingerprint check and FBI criminal history records, including fingerprint check, as well as a child abuse and neglect state registry check, if available. We also require programs to conduct complete background checks for each employee at least once every five years.

We believe programs require more time to implement systems to complete the background checks process listed at 45 CFR 1302.90(b)(2), (4), and (5) in our final rule. We aligned our compliance date for our background checks requirements with the background check requirement deadline the CCDBG Act because states that receive CCDBG funds are required to establish systems that implement the same set of comprehensive background checks for all child care teachers and staff. These systems will enable Head Start programs to meet background check requirements in the final rule.

We understand, however, states may request additional time-limited waivers of up to two years, in one year increments (i.e., potentially through September 30, 2020) to design systems that can accommodate our programs’ background checks requests. To minimize burden on programs, we will
extend the compliance date for 45 CFR 1302.90(b) to September 30, 2019. However, until Head Start programs have systems in place that fully comply with 45 CFR 1302.90(b), we require them to continue to adhere to the criminal record check requirements in section 648A of the Head Start Act, as amended by the Improving Head Start for School Readiness Act of 2007, Public Law 110–134.

**QRIS Requirement in the Final Rule**

We require programs that meet certain conditions, except for American Indian and Alaska Native programs, to participate in state or local QRIS, as prescribed at 45 CFR 1302.53(b)(2) in the final rule. A QRIS is a systemic approach to assess, improve, and communicate the level of quality in early and school-age care and education programs within a state or locality. It awards quality ratings to programs that meet a set of criteria as defined by the QRIS. Criteria Head Start programs must meet to enter the QRIS and maintain participation greatly vary by state. We recognize many Head Start programs were already participating in their state and local quality improvement efforts before we introduced this standard to the final rule. Now that we have included this standard in the final rule, we understand programs have taken steps to participate in QRIS and that many states are assessing their QRIS with new Head Start QRIS participation policies. However, programs and states need additional time to align these systems. We want to minimize any unintentional burden on states that choose to adapt their systems to allow Head Start programs to participate in QRIS, as well as alleviate programs’ concerns about meeting the current compliance date. To avoid duplication efforts between Head Start and QRIS monitoring systems as well as eliminate undue burden on Head Start programs and states as they work to align these systems, we will delay the compliance date for this standard for another year.

**Conclusion**

We ordinarily publish a notice of proposed rulemaking in the Federal Register to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons for this finding in the notice.

We find good cause to waive public comment under section 553(b) of the APA because it is unnecessary and contrary to the public interest to provide for public comment in this instance. States, localities, and Head Start grantees will likely be subjected to undue and unnecessary administrative burden as they expend time trying to find ways to implement these standards without support from local and state law enforcement agencies and without QRIS systems that can accommodate Head Start programs. A period for public comment would only extend programs’ concerns as they attempt to meet these standards by the compliance dates. Head Start programs are still required to comply with statutory background check requirements in the Improving Head Start for School Readiness Act of 2007, Public Law 110–134, until they can develop systems that will enable them to conduct complete background checks with fingerprints. Therefore, if we delay compliance dates, we will pose no harm or burden to programs or the public. Moreover, programs that already have systems in place to meet background check standards at 45 CFR 1302.90(b) and to participate in their states’ QRIS at 45 CFR 1302.53(b)(2) may voluntarily come into compliance by the compliance date. However, programs that do not have systems in place have until September 30, 2019 to comply.

Dated: September 14, 2018.


Alex M. Azar II, Secretary.

**SUPPLEMENTARY INFORMATION:**

FOR FURTHER INFORMATION CONTACT:


The 2018 total allowable catch (TAC) of Pacific ocean perch in the Western Regulatory Area of the GOA is 3,312 metric tons (mt) as established by the final 2018 and 2019 harvest specifications for groundfish of the Gulf of Alaska (83 FR 8768, March 1, 2018). In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 TAC of Pacific ocean perch in the Western Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 3,212 mt, and is setting aside 100 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the Western Regulatory Area of the GOA. While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

**Classification**

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5
U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for Pacific ocean perch in the Western Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 20, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 et seq.

Alan D. Risenhoover,
Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
50 CFR Part 679
[Docket No. 170816769–8162–02]
RIN 0648–XG505
Fisheries of the Exclusive Economic Zone Off Alaska; Dusky Rockfish in the Western Regulatory Area of the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for dusky rockfish in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2018 total allowable catch of dusky rockfish in the Western Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), September 21, 2018, through 2400 hours, A.l.t., December 31, 2018.

FOR Further INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 TAC of dusky rockfish in the Western Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 100 mt, and is setting aside the remaining 46 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for dusky rockfish in the Western Regulatory Area of the GOA.

While this closure is in effect the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for dusky rockfish in the Western Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 21, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 et seq.

Margo B. Schulze-Haugen,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
50 CFR Part 679
[Docket No. 170816769–8162–02]
RIN 0648–XG504
Fisheries of the Exclusive Economic Zone Off Alaska; Northern Rockfish in the Western Regulatory Area of the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for northern rockfish in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the 2018 total allowable catch of northern rockfish in the Western Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), September 21, 2018, through 2400 hours, A.l.t., December 31, 2018.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2018 total allowable catch (TAC) of northern rockfish in the Western Regulatory Area of the GOA is 146 metric tons (mt) as established by the final 2018 and 2019 harvest specifications for groundfish of the (83 FR 8768, March 1, 2018).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 TAC of dusky rockfish in the Western Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 100 mt, and is setting aside the remaining 46 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for dusky rockfish in the Western Regulatory Area of the GOA.

While this closure is in effect the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for dusky rockfish in the Western Regulatory Area of the GOA.

Therefore, the Regional Administrator finds that the 2018 TAC of"
specifications for groundfish of the (83 FR 8768, March 1, 2018).

In accordance with §679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2018 TAC of northern rockfish in the Western Regulatory Area of the GOA will be soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 50 mt, and is setting aside 370 mt as bycatch to support other anticipated groundfish fisheries. In accordance with §679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for northern rockfish in the Western Regulatory Area of the GOA.

While this closure remains in effect, the maximum retainable amounts at §679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for northern rockfish in the Western Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 20, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by §679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 et seq.


Margo B. Schulze-Haugen,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–20953 Filed 9–21–18; 4:15 pm]

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170816769–8162–02]

RIN 0648–XG501

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Hook-and-Line Catcher/Processors in the Western Regulatory Area of the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by hook-and-line catcher/processors in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the annual allowance of the 2018 Pacific cod total allowable catch apportioned to hook-and-line catcher/processors in the Western Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), September 21, 2018, through 2400 hours, A.l.t., December 31, 2018.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.


The annual allowance of the 2018 Pacific cod total allowable catch (TAC) apportioned to hook-and-line catcher/processors in the Western Regulatory Area of the GOA is 1,103 metric tons (mt), as established by the final 2018 and 2019 harvest specifications for groundfish of the GOA (83 FR 8768, March 1, 2018).

In accordance with §679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the annual allowance of the 2018 Pacific cod TAC apportioned to hook-and-line catcher/processors in the Western Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 1,090 mt and is setting aside the remaining 13 mt as bycatch to support other anticipated groundfish fisheries. In accordance with §679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by hook-and-line catcher/processors in the Western Regulatory Area of the GOA. While this closure is effective the maximum retainable amounts at §679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the directed fishing closure of Pacific cod by hook-and-line catcher/processors in the Western Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of September 20, 2018.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by §679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 et seq.


Margo B. Schulze-Haugen,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2018–20952 Filed 9–21–18; 4:15 pm]
This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL DEPOSIT INSURANCE CORPORATION
12 CFR Parts 327 and 337
RIN 3064–AE89
Limited Exception for a Capped Amount of Reciprocal Deposits From Treatment as Brokered Deposits

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The FDIC seeks comment on a notice of proposed rulemaking to conform its current regulations that implement brokered deposits and interest rate restrictions with recent changes to section 29 of the Federal Deposit Insurance Act made by section 202 of the Economic Growth, Regulatory Relief, and Consumer Protection Act related to reciprocal deposits, which took effect on May 24, 2018. Conforming amendments to the FDIC’s regulations governing deposit insurance assessments are also being proposed. This rulemaking is the first part of a two-part effort to revisit the brokered deposit rules. The FDIC is currently working on the second part, which is planned for later this year and which will seek comment on the brokered deposit regulations more generally. We encourage comments not related to the implementation of section 202 to be submitted as part of the broader rulemaking effort.

DATES: Comments on the rules must be received by October 26, 2018.

ADDRESSES: You may submit comments, identified by RIN 3064–AE89, by any of the following methods:

• Agency Website: http://www.FDIC.gov/regulations/laws/federal/.

• Mail: Robert E. Feldman, Executive Secretary, Attention: Comments/Legal ESS, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

• Hand Delivery/Courier: Comments may be hand-delivered to the guard station at the rear of the 550 17th Street NW building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

• Email: comments@FDIC.gov.

Instructions: Comments submitted must include “FDIC” and “RIN 3064–AE89.” Comments received will be posted without change to http://www.FDIC.gov/regulations/laws/federal/, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Division of Risk Management Supervision—Thomas F. Lyons, Chief, Policy and Program Development, (202) 898–6850, tlyons@fdic.gov; Judy Gross, Senior Policy Analyst, (202) 898–7047, jugross@fdic.gov; Division of Insurance and Research—Ashley Mihalik, Senior Policy Analyst, (202) 898–3793, amihalik@fdic.gov; Legal Division—Vivek V. Khare, Counsel, (202) 898–6847, vkhare@fdic.gov; Thomas Hearn, Counsel, (202) 898–6967; thearn@fdic.gov.

SUPPLEMENTARY INFORMATION:

I. Policy Objectives

The policy objective of this proposed rule is to implement section 202 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (the Act) enacted on May 24, 2018.2 Section 202 of the Act amends section 29 of the Federal Deposit Insurance Act (FDI Act)3 to except a capped amount of reciprocal deposits from treatment as brokered deposits for certain insured depository institutions. In addition, section 202 ensures that the interest rate restrictions in section 29 remain applicable to any deposit, including reciprocal deposits, whether or not they fall under the limited exception. Section 202 was effective immediately upon enactment.

As more fully discussed below, well-capitalized institutions are not restricted from accepting or soliciting brokered deposits and have no restrictions on the rates they pay on deposits. However, under section 29, less than well-capitalized institutions may not accept or solicit brokered deposits and may not offer rates on any deposits that are significantly higher than the prevailing rates in the institution’s normal market area. Section 29 defines the term “deposit broker” and provides a list of exclusions to that term. Funds obtained through a deposit broker are considered brokered deposits. Section 202 amends section 29 to effectively provide that a capped amount of reciprocal deposits will not be considered funds obtained through a deposit broker for certain insured depository institutions, and thus such deposits will be non-brokered. Reciprocal deposits that do not meet the section 202 exception are brokered deposits under section 29.

At this time, institutions with reciprocal deposits that meet section 202’s limited exception can refer to the Supplemental Instructions provided as part of the June 30, 2018, Call Report Instructions for information on reporting reciprocal deposits under the new law.4 The Federal Financial Institutions Examination Council (FFIEC) has indicated that it anticipates issuing additional instructions regarding the application of section 202 to reciprocal deposits for purposes of reporting in the Call Report for September 30, 2018.

This rulemaking is the first part of a two-part effort to revisit the brokered deposit rules. The FDIC is currently working on the second part, which is planned for later this year and will seek comment on the brokered deposit regulations more generally.

A. Section 29 of the FDI Act

Under section 29 of the FDI Act, an insured depository institution is restricted from accepting deposits by or through a deposit broker unless the institution is well capitalized for Prompt Corrective Action (PCA).

3 See 12 U.S.C. 1831f.

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pursposes. The FDIC may waive this restriction if the insured depository institution is adequately capitalized; however, the restriction cannot be waived if the institution is undercapitalized. Section 29 also imposes restrictions on the deposit interest rates that an insured depository institution may offer if the institution is not well capitalized. These interest rate restrictions cannot be waived. Section 337.6 of the FDIC’s Rules and Regulations implements section 29 of the FDI Act. Through this regulation, the FDIC has largely tracked the statutory definition of “deposit broker” and its exceptions.

A “deposit broker,” as defined by section 29 of the FDI Act, includes “any person engaged in the business of placing deposits, or facilitating the placement of deposits, of third parties with insured depository institutions or the business of placing deposits with insured depository institutions for the purpose of selling interests in those deposits to third parties . . . .” Under the FDIC’s regulations, a “brokered deposit” is thus defined as a deposit accepted through a “deposit broker.” The definition of “deposit broker” is subject to ten statutory exceptions in section 29 and one regulatory exception.

B. Reciprocal Deposits

The reciprocal deposit arrangement is based upon a network of banks that place funds at other participating banks and would not be eligible to be excepted from treatment as brokered deposits.

III. Discussion of Treatment of Reciprocal Deposits Under the Act

Prior to enactment of the Act, all reciprocal deposits were classified as brokered deposits. Section 202 of the Act amends section 29 of the FDI Act to except a capped amount of reciprocal deposits from treatment as brokered deposits for certain insured depository institutions. Section 202’s amendments took effect upon enactment on May 24, 2018, and the FDIC is proposing to amend its regulations to conform with the statutory amendments.

Section 202 defines “reciprocal deposits” as “deposits received by an agent institution through a deposit placement network with the same maturity (if any) and in the same aggregate amount as covered deposits placed by the agent institution in other network member banks.” Network member banks may receive other deposits through a network such as (1) deposits received without the institution placing into the network a deposit of the same maturity and same aggregate amount (sometimes referred to as “one-way network deposits”) and (2) deposits placed by the institution into the network where the deposits were obtained, directly or indirectly, by or through a deposit broker. Such other network deposits meet the definition of brokered deposits but would not meet the definition of reciprocal deposits and thus would not be eligible to be excepted from an institution’s brokered deposits under section 202.

In this rulemaking, the FDIC is proposing to implement section 202’s limited exception by incorporating these statutory definitions into section 337.6(e)(2) of the brokered deposit rules, without change. These definitions must be satisfied in order for a capped amount of reciprocal deposits to be excepted from treatment as brokered deposits.

A. Deposit Placement Network, Covered Deposits, and Network Member Bank

The term “deposit placement network” is defined in section 202 as a network in which an insured depository institution participates, together with other insured depository institutions, for the processing and receipt of reciprocal deposits. Institutions that are members of the deposit placement network are “network member banks.” The deposits that an “agent institution” places at other banks in return for reciprocal deposits are termed “covered deposits” under section 202. The term covered deposit is defined as a deposit that (1) is submitted for placement through a deposit placement network and (2) does not consist of funds that were obtained for the agent institution, directly or indirectly, by or through a deposit broker before submission for placement through the deposit placement network.

B. Agent Institution

Consistent with section 202, proposed section 337.6(e)(2) defines “agent institution” as an insured depository institution that places a covered deposit through a deposit placement network at other insured depository institutions in amounts that are less than or equal to the standard maximum deposit insurance amount, and specifies the

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5 12 U.S.C. 1831f(a).
6 12 U.S.C. 1831f(c).
7 12 U.S.C. 1831f.
9 12 CFR 337.6(a)(2).
11 12 CFR 337.6(a)(5)(ii)(B); see also, 57 FR 23933–01.
12 See FDIC Advisory Opinion No. 03–03 (July 29, 2003).
13 Except of the definition of “deposit broker.”
14 See FDIC’s 2011 Study on Core and Brokered Deposits, issued July 2011, Sections I.V.E. and VII.E.
15 79 FR 9525 (March 4, 2009).
16 Id. at 9532.
17 Generally, an established small bank is a small institution that has been federally insured for at least five years. See 81 FR 32180 (May 20, 2016).
18 12 CFR 327.6(a)(1)(ii).
19 See FDIC’s 2011 Study on Core and Brokered Deposits, issued July 2011, Section IV.
interest rate to be paid for such amounts, if the insured depository institution:
• Is well capitalized and has a composite condition of outstanding (CAMELS “1”) or good (CAMELS “2”) when most recently examined under section 10(d) of the FDI Act (described as “well rated”);21
• has obtained a waiver pursuant to section 29(c) of the FDI Act; or
• does not receive an amount of reciprocal deposits that causes the total amount of reciprocal deposits held by the agent institution to be greater than the average of the total amount of reciprocal deposits held by the agent institution on the last day of each of the four calendar quarters preceding the calendar quarter in which the agent institution was found not to have a composite condition of outstanding or good or was determined to be not well capitalized.

C. Caps Applicable to Agent Institutions
Consistent with section 202, under the proposed regulation, an “agent institution” can except reciprocal deposits from being classified as brokered deposits up to its applicable statutory caps, as explained below.

General Cap
An agent institution may except reciprocal deposits up to the lesser of the following amounts (referred to as the general cap) from being classified as brokered deposits: 22
• $5 billion or
• An amount equal to 20 percent of the agent institution’s total liabilities.

Reciprocal deposits in excess of the general cap, as well as those reciprocal deposits that do not meet section 202’s limited exception, are brokered deposits.

Special Cap
A special cap applies if the institution is either not well rated or not well capitalized. In this case, the institution may meet the definition of “agent institution” by maintaining its reciprocal deposits at or below the special cap, which is the average amount of reciprocal deposits held at quarter-end during the last four quarters preceding the quarter that the institution fell below well capitalized or well rated. The FDIC notes that section 202 does not provide a date by which an institution must demonstrate that its amount of reciprocal deposits are within the special cap. The FDIC is considering evaluating whether an institution’s reciprocal deposits meet the special cap based on information reported in its Call Reports. For an institution that is determined to fall below well rated, the FDIC would evaluate its compliance with the special cap based on Call Report data submitted for the reporting date immediately following when the determination is made. The FDIC seeks comment on any unintended consequences this may cause to institutions.

Application of Statutory Caps
Below are descriptions of how the two statutory caps would apply to an agent institution based upon its capital and composite ratings.

1. Well capitalized and well rated.
Institutions that are both well capitalized and well rated can have non-brokered reciprocal deposits up to the general cap. Any amount of reciprocal deposits over the general cap will no longer meet the limited exception and therefore that amount would be considered to be “brokered deposits.” Well-capitalized institutions can accept all brokered deposits, including reciprocal deposits that are brokered deposits, without any restrictions.

2. Not well capitalized or not well rated.
Institutions that are either not well capitalized or not well rated are subject to the lesser of either the special cap or the general cap. The amount of reciprocal deposits within the institution’s applicable cap would not be considered brokered deposits. In no event, however, can an institution’s non-brokered reciprocal deposits exceed the general cap. With respect to an institution that is well capitalized but not well rated, if it received reciprocal deposits above the special cap, it would no longer meet the definition of “agent institution.” In this situation, an institution would need to decide whether to (1) retain all of its reciprocal deposits and report them as brokered deposits (assuming the institution was well capitalized), or (2) lower the amounts of its reciprocal deposits to within the special cap by the end of the quarter that it is notified that it is no longer well rated, in which case all of the institution’s reciprocal deposits could be excepted from its brokered deposits. An institution that is less than adequately capitalized or adequately capitalized without a waiver would have the option to lower its reciprocal deposits to within the special cap by the end of the quarter for which, in the ordinary course, the change in capital status is reported, or work with its primary federal regulator to establish a supervisory plan for addressing reciprocal deposits. The FDIC requests comment on other ways an institution that is not well rated or not well capitalized could manage its holdings of reciprocal deposits in excess of the special cap, consistent with the applicable provisions of section 202 so that its reciprocal deposits would be treated as non-brokered.

D. Example of Section 202’s Applicability
A well rated and well capitalized community bank (“the Bank”) has a banking relationship with its local municipality. The municipality wishes to place deposits in excess of the standard maximum deposit insurance amount at the Bank. In an effort to provide insurance coverage for the entire amount of the deposit, the Bank offers the municipality the option to place its deposits through a deposit placement network at a specified interest rate.

In this case, the Bank is an “agent institution” because it is both well rated and well capitalized. After establishing itself as an “agent institution,” the Bank must next determine whether the municipal deposits that it wishes to submit into the deposit placement network are covered deposits. If the deposits are placed directly by the municipality, without any assistance of a third-party, the deposits meet the definition of a “covered deposit.”

Next, if the municipal deposits are “covered deposits,” to meet the statutory definition of “reciprocal deposits,” the institution must receive deposits with the same maturity (if any) and in the same aggregate amount as the covered deposits it placed with other network banks. If the definitional framework set forth in section 202 is satisfied, the Bank may except an amount of the deposits it receives from

21 The effective date of a CAMELS composite rating is the date of written notification to the institution by its primary federal regulator or state authority of its supervisory rating. See e.g., 12 CFR 327.4(f).
23 12 U.S.C. 1831f(c). Institutions that are adequately capitalized may seek a waiver from the FDIC to accept brokered deposits. Waivers under section 29(c) are only available (1) on a case-by-case basis, (2) upon application to the FDIC, (3) to adequately capitalized institutions, and (4) upon a finding that the acceptance of such deposits does not constitute an unsafe or unsound practice with respect to such institution. Less than adequately capitalized institutions (undercapitalized or significantly undercapitalized institutions) are not eligible to seek a waiver from the FDIC.
the deposit network—up to the general cap—from treatment as brokered deposits.

In contrast to the example described above, if the Bank places deposits obtained by or through the assistance of a deposit broker into a deposit placement network, then those deposits would not meet the definition of a “covered deposit.” As a result, deposits that the Bank receives in exchange for its brokered deposits from other network member banks would not qualify as “reciprocal deposits” and therefore would not meet section 202’s limited exception.

E. Conforming Assessments Amendments

The FDIC is proposing to make conforming amendments to its assessments regulations to be consistent with the statutory definition of reciprocal deposits. Prior to enactment of section 202, all reciprocal deposits as defined in the assessment regulations met the definition of brokered deposits. Because section 202 excepts certain reciprocal deposits from treatment as brokered deposits, the FDIC is proposing to replace the current definition of “reciprocal deposits” in section 327.8(q) with a new term, “brokered reciprocal deposit.” A “brokered reciprocal deposit” is a “reciprocal deposit” as defined under section 202, and proposed section 337.6(e)(2)(iv), that does not meet the statute’s limited exception (e.g., deposits over the applicable caps discussed above). The FDIC is also proposing to make conforming amendments to sections 327.16(a)(1)(ii) and 327.16(e)(3), which reference reciprocal deposits.

For assessment purposes, “brokered reciprocal deposits” will continue to be excluded from the brokered deposit ratio for established small institutions that are well capitalized and well rated. For new small banks and large and highly complex banks that are less than well capitalized or not well rated, “brokered reciprocal deposits” will continue to be included in an institution’s total brokered deposits for the brokered deposit adjustment.25

The FDIC notes that the statutory definition of “reciprocal deposit” is substantially similar to the current regulatory definition in Part 327, with one difference. Section 202’s definition of “reciprocal deposits” is limited to funds obtained from a deposit placement network in exchange for funds placed into the network that meet the definition of “covered deposits,” which excludes funds that were obtained, directly or indirectly, by or through a deposit broker before submission for placement through the deposit placement network. As such, funds that do not meet the statutory definition of “reciprocal deposit” because they are obtained in exchange for funds that the institution acquired by or through a deposit broker are “brokered deposits” and would not meet the proposed definition of “brokered reciprocal deposits.”

The FDIC seeks comment on the extent to which institutions may be affected by the FDIC’s proposal to conform the definition of reciprocal deposits for assessment purposes with the definition provided in section 202.

F. Interest Rates

Section 202 applies the statutory interest rate restrictions under section 29 to all reciprocal deposits. More specifically, section 202 amends section 29(e) of the FDI Act by ensuring that the interest rate restrictions apply to less than well capitalized banks that accept reciprocal deposits.26 As a result, section 202 confirms that the current statutory and regulatory rate restrictions for less than well capitalized institutions continue to apply to any deposit, including a reciprocal deposit that is a covered deposit. 27 To ensure consistent treatment of the interest rate restrictions under section 202, the FDIC is proposing conforming amendments to section 337.6(b)(2)(ii) of its rules and regulations.

IV. Expected Effects

As noted previously, section 202 of the Act took effect upon enactment, and the proposed rule would conform part 337 with the legislation and align the assessment rules with the statute’s definition of “reciprocal deposits.” The proposed rule applies to all FDIC-insured depository institutions. As of March 31, 2018, there were 5,616 FDIC-insured institutions. Of these, 2,528 institutions report having brokered deposits, which totaled $980 billion. Of the institutions reporting brokered deposits, 1,185 institutions also report having reciprocal deposits, totaling $48 billion.

Benefits

The proposed rule could affect deposit insurance assessments for a small number of FDIC-insured institutions. As discussed in Section II: Background, the brokered deposit ratio is one of the financial measures used to determine assessment rates for established small banks. The brokered deposit ratio may increase assessment rates for established small banks with brokered deposits greater than 10 percent of total assets. Among these banks, those that are well capitalized and well rated can already deduct reciprocal deposits from brokered deposits and generally would not be affected by the proposed rule, for assessment purposes. Furthermore, the proposed rule would not affect the assessment rates of banks that do not have reciprocal deposits or whose brokered deposits comprise less than 10 percent of total assets. The FDIC estimates that fewer than ten (0.178 percent) small FDIC-insured institutions that are either not well capitalized or not well rated (or both) could have a lower assessment rate under the proposed rule if their reciprocal deposits are excluded from brokered deposits.28 For large institutions, generally insured depository institutions with greater than $10 billion in total assets, the proposed rule may alter the core deposit ratio, resulting in a change in the bank’s assessment. 29 The FDIC estimates that 20 (0.356 percent) FDIC-insured institutions could have a lower assessment due to the effect of the proposed rule on their core deposit ratio, if their reciprocal deposits are excepted from treatment as brokered. Based on data as of March 31, 2018, the FDIC estimates that no more than 30 institutions would have reduced assessment rates, all else equal, and the FDIC’s aggregate assessment revenue

228 All else equal, a higher brokered deposit ratio will result in a higher assessment rate.

229 See 12 CFR 327.16(a)(3).


231 The core deposit ratio applies to large and highly-complex institutions and is measured as domestic deposits, excluding brokered deposits and uninsured non-brokered time deposits, divided by total liabilities. Reciprocal deposits that are brokered reciprocal deposits will continue to be excluded from the ratio. See 12 CFR 327.16(b) and Appendix B.
would be reduced by an estimated $4.3 million annually.

Adequately capitalized institutions may also benefit from the proposed rule through a reduction in administrative costs. Under existing regulations, these institutions must seek and receive a regulatory waiver from the FDIC in order to accept brokered deposits. The proposed rule would allow these institutions that previously accepted reciprocal deposits to continue to receive reciprocal deposits up to the lesser of the general or special cap, even though they are otherwise prohibited from receiving brokered deposits. Under existing regulations, undercapitalized institutions cannot solicit or accept any reciprocal deposits because all reciprocal deposits are treated as brokered deposits. Because the proposed rule excepts a certain amount of reciprocal deposits from treatment as brokered, undercapitalized institutions that, when better capitalized, previously accepted reciprocal deposits may now be allowed to receive reciprocal deposits up to the lesser of the general or special cap despite being undercapitalized. If undercapitalized institutions can receive reciprocal deposits, the result may be increased utilization of reciprocal deposits in the future. However, this effect is difficult to estimate with available data because the decision to receive reciprocal deposits depends on the specific financial conditions of each bank, fluctuating market conditions for reciprocal deposits, and future management decisions.

There are 2,528 (45 percent) institutions that report holding some amount of brokered deposits and 1,185 (21 percent) that report holding some amount of reciprocal deposits. The changes could affect some metrics that rely on the amount of brokered deposits reported on the Call Report, such as:

- Net Noncore Funding Dependence Ratio
- Brokered Deposits Maturing in less than year to Brokered Deposits Ratio
- Brokered Deposits to Deposits Ratio
- Listing Service and Brokered Deposits to Deposits Ratio
- Reciprocal Brokered Deposits to Total Brokered Deposits Ratio

Cost

With regards to the difference in the current regulatory definition of "reciprocal deposits" for assessment purposes, which was added pursuant to the FDIC’s assessment authority under section 7 of the FDI Act, and the statutory definition of reciprocal deposits that was added to section 29 of the FDI Act, the FDIC notes that banks do not report data on the amount (if any) of deposits that were obtained, directly or indirectly, by or through a deposit brokered before submission for placement through the deposit placement network. As a result, the FDIC cannot estimate whether this change to align the assessment regulation definition of “reciprocal deposits” with the statutory definition of that term in section 29 of the FDI Act would affect the amount of reciprocal deposits that a bank would report or whether it would affect any bank’s assessment rate.

With regards to costs to the Deposit Insurance Fund, the FDIC estimates that, assuming all currently reported reciprocals align with the statutory definition, all else equal, the FDIC’s aggregate assessment revenue would be reduced by an estimated $4.3 million annually. Additional reduced assessment revenue could occur if institutions shift their funding mix away from funding sources that affect assessment rates, such as brokered deposits, towards reciprocal deposits. Historically, when resolving failed institutions, the FDIC has found that potential acquiring institutions have generally been unwilling to pay a premium for reciprocal deposits, typically treating them consistent with other brokered deposits. It is not clear whether reciprocal deposits that are no longer considered brokered as a result of section 202 would be viewed by potential acquiring institutions as more akin to traditional retail deposits for purposes of warranting a premium. As a result, the FDIC requests comment on whether these non-brokered reciprocal deposits would be considered differently in the failing bank context. Additionally, the FDIC could pose some additional regulatory costs associated with changes to internal systems or processes, or changes to reporting requirements.

V. Alternatives

The FDIC considered alternatives to the proposed rule but believes that the proposed amendments represent the most appropriate option. In particular, the FDIC considered whether a rulemaking implementing section 202 was necessary or appropriate. Section 202’s amendments to section 29 became effective upon the Act’s enactment on May 24, 2018, so one view considered was whether a rulemaking was necessary to implement the amendments. However, the FDIC believes that conforming section 337.6 with section 202’s amendments will remove confusion that might arise if interested parties only consult section 337.6 for requirements related to brokered deposits.

Section 202 did not address the assessment rules in part 327 with respect to reciprocal deposits. However, the definition of “reciprocal deposits” in part 327 varies with the definition of that term in section 202. As an alternative, the FDIC considered whether it should continue to use the existing definition of “reciprocal deposits” for assessment purposes. However, the FDIC is concerned that having two different definitions of “reciprocal deposits” could cause confusion as well as undue burden in the industry, particularly for reporting purposes.

VI. Request for Comment

The FDIC seeks comment on its proposal to conform its current regulations that implement brokered deposit and interest rate restrictions with recent changes to section 29 made by section 202 of the Act. As noted earlier, this notice of proposed rulemaking is the first part of a two-part effort to revisit the brokered deposit rules. The FDIC is currently working on the second part, which is planned for later this year and which will seek comment on the brokered deposit regulations more generally. We encourage comments not related to the implementation of section 202 to be submitted as part of the broader rulemaking effort. The FDIC seeks comment on all aspects of this proposed rule and in particular the following questions that were provided in previous sections of this proposal.

- As indicated above, for an institution that is determined to not be well rated and can only meet the “agent institution” definition by maintaining its reciprocal deposits at or below the special cap, the FDIC is considering
evaluating this issue based on Call Report Data submitted for the reporting date immediately following when the determination is made. The FDIC seeks comment on any unintended consequences this approach may cause to institutions.

• The FDIC seeks comment on other ways an institution that is not well rated or not well capitalized could manage its holdings of reciprocal deposits in excess of the special cap, consistent with the applicable provisions of section 202’s definition of “agent institution,” so that its reciprocal deposits would be treated as non-brokered.

• The FDIC seeks comment on the extent to which institutions may be affected by the FDIC’s proposal to conform the definition of reciprocal deposits for assessment purposes with the definition provided in section 202.

• The FDIC requests comment on whether reciprocal deposits that are no longer considered brokered deposits as a result of section 202 would be viewed by a potential acquiring institution bidding on the deposits of a failed institution the same way it views traditional retail deposits for which a premium would be offered.

• The FDIC seeks comments on how the regulations should apply to de novo institutions that lack four prior quarters of reciprocal deposits to calculate the special cap.

VII. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106–102, 113 Stat. 1771 (Nov. 12, 1999), requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The FDIC invites your comments on how to make this revised proposal easier to understand. For example:

• Has the FDIC organized the material to suit your needs? If not, how could the material be better organized?

• Are the requirements in the proposed regulation clearly stated? If not, how could the regulation be stated more clearly?

• Does the proposed regulation contain language or jargon that is unclear? If so, which language requires clarification?

• Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand?

VIII. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 et seq., generally requires an agency, in connection with a proposed rule, to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities.34 However, a regulatory flexibility analysis is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) has defined “small entities” to include banking organizations with total assets of less than or equal to $550 million.35

As of March 31, 2018, there were 5,616 FDIC-insured institutions, of which 4,177 are considered small entities for the purposes of RFA.36

The proposed rule could affect deposit insurance assessments for a small number of FDIC-insured, small entities. As discussed in Section II: Background, the brokered deposit ratio is one of the financial measures used to determine assessment rates for established small banks. The brokered deposit ratio may increase assessment rates for established small banks with brokered deposits greater than 10 percent of total assets.37 Among these banks, those that are well capitalized and well rated can already deduct reciprocal deposits from brokered deposits and generally would not be affected by the proposed rule, for assessment purposes.38

Furthermore, the proposed rule would not affect the assessment rates of small banks that do not have reciprocal deposits or whose brokered deposits comprise less than 10 percent of total assets. The FDIC estimates that seven (0.2 percent) of FDIC-insured entities that are either not well capitalized or not well rated (or both) could have a lower assessment rate under the proposed rule if their reciprocal deposits are excepted from brokered deposits.39

There are 611 (14.6 percent) small entities that report holding some amount of reciprocal deposits and 1,499 (35.9 percent) that report holding some amount of brokered deposits. These changes could affect some metrics that rely on the amount of brokered deposits reported on the Call Report, such as:

• Net Noncore Funding Dependence Ratio

• Brokered Deposits Maturing in less than year to Brokered Deposits Ratio

• Brokered Deposits to Deposits Ratio

• Listing Service and Brokered Deposits to Deposits Ratio

• Reciprocal Brokered Deposits to Total Brokered Deposits Ratio

Based on available information, it is difficult to determine whether additional regulatory costs or costs to the Deposit Insurance Fund could result. Nonetheless, the proposed rule could pose some additional regulatory costs associated with changes to internal systems or processes, or changes to reporting requirements. Based on the information above, the FDIC certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The FDIC invites comments on all aspects of the supporting information provided in this RFA section. In particular, would this rule have any significant effects on small entities that the FDIC has not identified?

IX. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (PRA), the FDIC may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The FDIC has reviewed the proposed rule and determined that it revises certain reporting requirements that have been previously cleared by the OMB under various control numbers.40

On May 24, 2018, EGRRCPA amended various statutes administered by the Agencies and affected regulations issued

34 S U.S.C. 601 et seq
35 The SBA defines a small banking organization as having $550 million or less in assets, where “a financial institution’s assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.” See 13 CFR 121.201 (as amended, effective December 2, 2014). “SBA counts the receipts, employees, or other measure of size of the concern whose size is at issue and all of its domestic and foreign affiliates.” See 13 CFR 121.103. Following these regulations, the FDIC uses a covered entity’s affiliated and acquired assets, averaged over the preceding four quarters, to determine whether the covered entity is “small” for the purposes of RFA.
37 All else equal, a higher brokered deposit ratio will result in a higher assessment rate.
38 See 12 CFR 327.10(c)(1)(i).
40 The reporting requirements are found in the three Consolidated Reports of Condition and Income (Call Reports) promulgated by the Federal Financial Institutions Examination Council (FFIEC). The Call Reports are designated FFIEC 001 (Consolidated Report of Condition and Income for a Bank with Domestic and Foreign Offices); FFIEC 041 (Consolidated Report of Condition and Income for a Bank with Domestic Offices Only); and FFIEC 051 (Consolidated Report of Condition and Income for a Bank with Domestic Only and Total Assets of Less than $1 Billion). The FFIEC constituent bank regulatory agencies (the Board of Governors of the Federal Reserve System (the Board), the Office of the Comptroller of the Currency (the OCC) and the FDIC (the Agencies) have each obtained information collection clearances from OMB under the following Control Numbers: 7100–0036 (Board); 1557-0081 (OCC); and 3064–0052 (FDIC).
by the Agencies. As described above, certain amendments made by EGRRCPA took effect on the day of EGRRCPA’s enactment and immediately impacted institutions’ regulatory reports. In response to emergency review requests, the Agencies received approval from OMB to revise the reporting of information in the Call Reports including the reciprocal deposits provisions described in this proposed rule. As a result of OMB’s emergency approval of revisions to the information collections affected by the above statutory changes, the expiration date of these collections has been revised to February 28, 2019. The Agencies are now undertaking the regular PRA process for revising and extending these information collections for three years and plan to publish the required 60-day notice in the Federal Register.

X. Riegle Community Development and Regulatory Improvement Act

The Riegle Community Development and Regulatory Improvement Act of 1994 (RCIDRIA), 12 U.S.C. 4701, requires that each Federal banking agency, in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations. In addition, new regulations that impose additional reporting, disclosures, or other new requirements on insured depository institutions generally must take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form.

The changes relating to “reciprocal deposits” and section 29 were effective upon enactment of section 202, and as described previously, institutions have already begun reporting reciprocal deposits as per the new law. The FDIC anticipates that any final rule relating to the amendments to part 337 of the FDIC’s assessments regulations in part 327. The FDIC is inviting comment on any administrative burdens that the proposed changes would place on depository institutions, including small depository institutions, and customers of depository institutions. The FDIC will consider these comments in connection with determining an effective date for the proposed rule. Consistent with RCIDRIA, the FDIC anticipates that any changes to the assessment rule would be effective on the first day of a calendar quarter that begins after the date on which a final rule is published.

List of Subjects

12 CFR Part 327
Bank deposit insurance, Banks, Banking, Savings associations.

12 CFR Part 337
Banks, Banking, Reporting and recordkeeping requirements, Savings associations.

For the reasons stated in the preamble, the FDIC hereby proposes to amend parts 327 and 337 as follows:

PART 327—ASSESSMENTS

1. The authority for 12 CFR part 327 continues to read as follows:


2. Amend § 327.8 by revising paragraph (q) to read as follows:

   § 327.8 Definitions.
   * * * * *

   (q) Brokered reciprocal deposits—Reciprocal deposits as defined in § 337.6(e)(2)(v) that are not excepted from the institution’s brokered deposits pursuant to § 337.6(e).
   * * * * *

   § 327.16 [Amended]

3. Amend § 327.16, by removing “reciprocal deposit” and adding in its place “brokered reciprocal deposit as defined in section 327.8(p)” in paragraph (a)(1)(ii) and by removing “reciprocal deposits as defined in § 327.8(p)” and adding in its place “brokered reciprocal deposits as defined in section 327.8(q)” in paragraph (e)(3).

PART 337—UNSAFE AND UNSOUND BANKING PRACTICES

4. The authority for 12 CFR part 337 continues to read as follows:

   Authority: 12 U.S.C. 375a(4), 375b, 1463a(11), 1816, 1818(a), 1818(b), 1819, 1820(d), 1828(j)(3), 1831, 1831f, 5412.

5. Amend § 337.6 by revising paragraph (b)(2)(ii) introductory text, redesignating paragraph (e) as paragraph (f), and adding a new paragraph (e) to read as follows:

   § 337.6 Brokered deposits.
   * * * * *

   (b) * * *

   (2) * * *

   (ii) Any adequately capitalized insured depository institution that has been granted a waiver to accept, renew or roll over a brokered deposit, or is an agent institution that receives a reciprocal deposit (under § 337.6(e)(2)(i)(C)), may not pay an effective yield on any such deposit which, at the time that such deposit is accepted, renewed or rolled over, exceeds by more than 75 basis points:
   * * * * *

   (e) Limited exception for reciprocal deposits. (1) Limited exception.

   Reciprocal deposits of an agent institution shall not be considered to be funds obtained, directly or indirectly, by or through a deposit broker to the extent that the total amount of such reciprocal deposits does not exceed the lesser of:
   (i) $5,000,000,000; or
   (ii) An amount equal to 20 percent of the total liabilities of the agent institution.

   (2) Additional definitions that apply to the limited exception for reciprocal deposits—(i) Agent institution means an insured depository institution that places a covered deposit through a deposit placement network at other insured depository institutions in amounts that are less than or equal to the standard maximum deposit insurance amount, specifying the interest rate to be paid for such amounts, if the insured depository institution:

   (A) When most recently examined under section 10(d) of the Federal Deposit Insurance Act (12 U.S.C. 1820(d)) was found to have a composite condition of outstanding or good; and
   (B) Is well capitalized;

   (ii) Has obtained a waiver pursuant to paragraph (c) of this section; or

   (C) Does not receive an amount of reciprocal deposits that causes the total amount of reciprocal deposits held by the agent institution to be greater than the average of the total amount of reciprocal deposits held by the agent institution on the last day of each of the four calendar quarters preceding the calendar quarter in which the agent institution was found not to have a composite condition of outstanding or good or was determined to be not well capitalized.

   (ii) Covered deposit means a deposit that:

(A) Is submitted for placement through a deposit placement network by an agent institution; and
(B) Does not consist of funds that were obtained for the agent institution, directly or indirectly, by or through a deposit broker before submission for placement through a deposit placement network.

(iii) Deposit placement network means a network in which an insured depository institution participates, together with other insured depository institutions, for the processing and receipt of reciprocal deposits.

(iv) Network member bank means an insured depository institution that is a member of a deposit placement network.

(v) Reciprocal deposits means deposits received by an agent institution through a deposit placement network with the same maturity (if any) and in the same aggregate amount as covered deposits placed by the agent institution in other network member banks.

Dated at Washington, DC, on September 12, 2018.
Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

[FR Doc. 2018–20303 Filed 9–25–18; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1271
RIN 2590–AA99

Miscellaneous Federal Home Loan Bank Operations and Authorities—Financing Corporation Assessments

AGENCY: Federal Housing Finance Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Housing Finance Agency (FHFA) is proposing to amend its regulations pertaining to the operation of the Financing Corporation (FICO), a vehicle established by one of FHFA’s predecessors to issue bonds, the proceeds of which were used to help fund the resolution of failed savings and loan associations during the 1980s. The last of those FICO bonds will mature in September 2019. By statute, FICO obtains the monies to pay the interest on those bonds by assessing depository institutions (FICO assessments) that are insured by the Federal Deposit Insurance Corporation (FDIC). The proposed rule addresses the manner in which FICO would conduct the 2019 FICO assessments, which are expected to be the last of those assessments. Specifically, the proposed rule would provide that all payments made by FDIC-insured depository institutions during 2019 will be final, and that no adjustments to prior FICO assessments would be permitted after March 26, 2019, the projected date as of which the FDIC will finalize the amounts of the final collection for the 2019 FICO assessments.

DATES: FHFA must receive written comments on or before October 26, 2018.

ADDRESSES: You may submit your comments on the proposed rule, identified by regulatory information number (RIN) 2590–AA99 by any of the following methods:

• Agency Website: www.fhfa.gov/open-for-comment-or-input.
• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. If you submit your comments to the Federal eRulemaking Portal, please also send it by email to FHFA at RegComments@FHFA.gov to ensure timely receipt by the agency. Please include “RIN 2590–AA99” in the subject line of the message.

• Hand Delivery/Courier: The hand delivery address is: Alfred M. Pollard, General Counsel, Attention: Comments/ RIN 2590–AA99, Federal Housing Finance Agency, Constitution Center, (OGC) Eighth Floor, 400 Seventh Street SW, Washington, DC 20219. The package should be delivered to the Seventh Street entrance Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.

• U.S. Mail, United Parcel Service, Federal Express, or Other Mail Service: The mailing address for comments is: Alfred M. Pollard, General Counsel, Attention: Comments/ RIN 2590–AA99, Federal Housing Finance Agency, Constitution Center, (OGC) Eighth Floor, 400 Seventh Street SW, Washington, DC 20219.

FOR FURTHER INFORMATION CONTACT: Louis M. Scalza, Associate Director, Examinations, Office of Safety & Soundness Examinations, Louis.Scalza@ fhfa.gov, (202) 649–3710; Winston Sale, Assistant General Counsel, Winston.Sale@fhfa.gov, (202) 649–3081; or Neil R. Crowley, Deputy General Counsel, Neil.Crowley@fhfa.gov, (202) 649–3055 (these are not toll-free numbers), Federal Housing Finance Agency, 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. Comments

FHFA invites comment on all aspects of the proposed rulemaking, which FHFA is publishing with a 30-day comment period. After considering the comments, FHFA will develop a final regulation. Copies of all comments received will be posted without change on the FHFA website at http://www.fhfa.gov, and will include any personal information you provide, such as your name, address, email address, and telephone number.

II. Background

FHFA is an independent agency of the federal government established to regulate and oversee the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation, the Federal Home Loan Banks (Banks), and the Bank System’s Office of Finance.1 FHFA also is responsible for overseeing FICO. The Competitive Equality Banking Act of 19872 amended the Federal Home Loan Bank Act (Bank Act) and authorized FHFA’s predecessor to establish FICO, and authorizes the FHFA Director to select the two Bank presidents that serve on its directorate, to prescribe such regulations as are necessary to carry out the statutory provisions relating to FICO, and to oversee the dissolution of FICO.3

FICO is a mixed-ownership, tax-exempt government corporation, chartered in 1987 by the former Federal Home Loan Bank Board, one of FHFA’s predecessor agencies, pursuant to the Federal Savings and Loan Insurance Corporation (FSLIC) Recapitalization Act of 1987, as amended (Recapitalization Act).4 The Recapitalization Act’s purpose was to recapitalize the FSLIC insurance fund, which had been significantly depleted by a wave of savings and loan (S&L) failures during the S&L crisis of the 1980s. FICO’s mission was to provide funding for FSLIC (and later for the FSRC Resolution Fund) in the event of an S&L’s insolvency and later abolishment by the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA) by selling bonds to the public. FICO’s operations are managed by a directorate composed of the Director of the Office of Finance and two Bank presidents

3 See 12 U.S.C. 1441(a) (establishment of FICO), (b)(B) (selection of directors), (i) (dissolution, and authority for FHFA to exercise any FICO powers, needed to conclude its affairs), and (j) (authority to prescribe regulations).
who rotate after serving one year terms.\(^5\) FICO has no permanent staff and utilizes Office of Finance staff to execute its day-to-day functions. FICO was initially capitalized by issuing stock to the Banks in an aggregate amount of $680 million, apportioned pro rata among the Banks in accordance with a statutory formula.\(^6\) FICO used the proceeds from the stock issuances to purchase U.S. Treasury zero-coupon securities (Zeros), which were to be the sole source of repayment of the principal of the bonds to be issued by FICO. Between 1987 and 1989, FICO issued 14 separate series of 30-year bonds (Obligations) in an aggregate principal amount of approximately $8.1 billion. FICO conveyed the proceeds of the Obligations to FSLIC, to finance its resolution of failed S&Ls.\(^7\) FICO is required by statute to hold the Zeros in a segregated account until they are used to pay the principal due on the Obligations at their maturity.\(^8\) The Obligations began to mature in 2017, and the last Obligation will mature in September 2025.

The Recapitalization Act established a different source for providing funds needed to service the semiannual interest payments on the FICO Obligations.\(^9\) The statute authorized FICO to assess FSLIC-insured depository institutions for the funds needed to pay the interest due on the FICO Obligations.\(^10\) The Deposit Insurance Funds Act of 1996 authorized FICO to assess against institutions with deposits insured by both the Bank Insurance Fund (BIF) and the Savings Association Insurance Fund (SAIF).\(^11\) Pursuant to the Federal Deposit Insurance Reform Act of 2005, effective March 31, 2006, the BIF and SAIF were merged into the newly created Deposit Insurance Fund (DIF), and thus FICO may assess institutions insured by the DIF.\(^12\) FICO is authorized to assess insured depository institutions only for three purposes: For making interest payments on the FICO Obligations; paying insurance costs for the FICO Obligations; and paying custodial fees associated with the FICO Obligations. The Bank Act, as amended by FIRREA, further provides that FICO is to conduct its assessments in the same manner that the FDIC uses when assessing its insured depository institutions for deposit insurance purposes.\(^13\) FICO and the FDIC entered into a memorandum of understanding in 1997 (Memorandum of Understanding), as amended in 1999, pursuant to which the FDIC collects FICO’s assessments from its insured depository institutions quarterly, as agent for FICO.

The FDIC conducts its own Deposit Insurance Fund assessments quarterly (FDIC assessment), with the amount of the FDIC assessment for each insured depository institution being determined based, in part, on data that the institution has submitted to the Federal Financial Institutions Examination Council (FFIEC) in its Consolidated Reports of Condition and Income (call report). If an insured depository institution amends a call report on which a previous FDIC assessment had been calculated and the amendment to the call report would cause the calculation of the prior FDIC assessment to change, the institution may receive an adjustment, which generally appears on an upcoming invoice.\(^14\) Pursuant to the Memorandum of Understanding, the FDIC divides the FICO assessments among FDIC-insured institutions quarterly, as agent for FICO, at the same time as the collection of FDIC assessments. Pursuant to the Memorandum of Understanding, FICO assessments are made based on an assessment rate formula adopted by FICO, and approved by the FDIC Board of Directors. One factor in FICO’s formula is the deposit insurance assessment base, which (as described above) is calculated using an insured depository institution’s call report data. Under the terms of the Memorandum of Understanding, twice per year, FICO notifies the FDIC of the total amounts that would be needed for FICO to make its upcoming Obligation interest payments and annually informs the FDIC of the interest it has earned. Using that information and FICO’s assessment rate formula, the FDIC calculates a “quarterly multiplier” and applies it to information derived from each institution’s call report to determine the FICO assessment for each insured depository institution for that calendar quarter. The FDIC then issues an invoice to each insured depository institution detailing both its quarterly FDIC and FICO assessments.\(^15\) Insured depository institutions submit payment for their FDIC and FICO assessments to the FDIC via ACH. The FDIC then transfers the aggregate FICO collections to an account that FICO maintains at the Federal Reserve Bank of New York, from which FICO pays the interest that is due on the FICO Obligations.

In the case of an insured depository institution that amends its call report for a prior period, FICO assessments are adjusted in the same manner as FDIC assessments. Thus, if an amended call report results in an institution having overpaid or underpaid a prior quarter’s FICO assessment an adjustment amount will appear on an upcoming invoice, provided that the amendment has been made within three years after the date that the associated FICO payment was due.\(^16\) Pursuant to the Memorandum of Understanding, overpayments arising from amended call reports are generally credited against the next quarter’s FICO assessment and underpayments are added to the next quarter’s FICO assessment.

With respect to all such refunds for overpayments of prior period FICO assessments once all FICO obligations are paid, however, FICO has no legal obligation to use its own assets (other than those funds obtained from the FICO assessments) to provide monies to any insured depository institutions to make those refunds and does not do so. Indeed, FICO has no legal authority to assess insured depository institutions for the sole purpose of obtaining monies to provide refunds to other insured depository institutions or to spend its own non-assessment assets for that purpose. As a practical matter, because these refunds are processed as credits against the next FICO assessment, they do not require any cash outlay from FICO and all refunds are effectively paid

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\(^7\) FICO used the net proceeds from the first 13 series of its Obligations to purchase nonredeemable capital certificates and nonredeemable nonvoting capital stock issued by the FSLIC. After the FSLIC was abolished in 1989, FICO used the proceeds from its final Obligation to purchase nonredeemable capital certificates issued by the FSLIC Resolution Fund, the statutory successor to the FSLIC. See 12 U.S.C. 1821a (establishment of FSLIC Resolution Fund). Those instruments have no value and have been charged to FICO’s capital.

\(^8\) See 12 U.S.C. 1441(g)(2).

\(^9\) Interest on each FICO Obligation is paid on the anniversary of its issuance date, and six months after that date each year.

\(^10\) 12 U.S.C. 1441(f)(2). The statute further provides that the FICO assessments are subject to the approval of the FDIC board of directors. FICO and the FDIC have entered into a memorandum of understanding under which FDIC, as agent for FICO, collects the FICO assessments on insured depository institutions, as approved by the FDIC.

\(^11\) See 12 U.S.C. 1441(f)(3). FICO used the proceeds from the stock issuances to purchase U.S. Treasury zero-coupon securities (Zeros), which were to be the sole source of repayment of the principal of the bonds to be issued by FICO.

\(^12\) Public Law 109–171 sec. 2109(a)(2), 120 Stat. 20.


\(^14\) See 12 U.S.C. 1817(g)(2) (establishing a three-year statute of limitations on actions by insured depository institutions to recover overpayments from FDIC, and on actions by FDIC to recover underpayments from the insured institutions).

\(^15\) The FDIC provides to each institution a Quarterly Certified Statement Invoice that specifies the total amount of that quarter’s assessment, including the FDIC assessment and the FICO assessment for that calendar quarter.

\(^16\) See 12 U.S.C. 1817(g)(2) (establishing a three-year statute of limitations on actions by insured depository institutions to recover overpayments from FDIC, and on actions by FDIC to recover underpayments from the insured institutions).
from the assessments on the other insured depository institutions collectively. The principal effect of such refunds is that they modestly reduce the amount of monies actually collected by the FDIC, as agent for FICO, as part of a particular quarter’s FICO assessment. Those refund credits, however, may be offset by the additional amounts that the FDIC collects, as an agent for FICO, from other institutions that had previously underpaid a prior FICO assessment. To the extent overpayment credits exceed underpayment collections, such shortfall is made up the following quarter by increasing the total collection amount accordingly. Moreover, because the determination of the quarterly multiplier for setting the FICO assessment involves rounding, any quarterly collection of the FICO assessment may yield slightly more money than the initially projected assessment amount. Pursuant to the Memorandum of Understanding with the FDIC, FICO also maintains a cash reserve that is available to make up modest shortfalls that might arise during a quarterly collection. FICO has never needed to use the cash reserve, because it has always collected sufficient funds to make all required interest payments when due. FHFA anticipates that FICO will draw down the monies in its cash reserve to fund a portion of the remaining interest payments on its Obligations as they come due, which also would reduce the amount needed to be assessed and collected from insured depository institutions during 2019.

As is evident from the above description, the current practice for adjusting individual FICO assessments—to account for either refunds or additional collections—depends on the existence of a subsequent FICO collection that could serve as the source of funds and the means by which any such adjustments may be processed. The last of the FICO bonds will mature during 2019 and FICO is scheduled to make five different interest payments during 2019. FHFA anticipates that the FDIC, as agent for FICO, will collect one FICO assessment during 2019 and that the amounts received by FICO from the March 2019 collections will be sufficient (when combined with any other available funds that FICO will have on hand) to make all remaining interest payments due during 2019. Accordingly, once the final FICO assessment has been collected, there will be no subsequent billing cycle through which an insured depository institution could have a prior FICO assessment adjusted, i.e., the FDIC, which will cease to be collection agent for FICO, will no longer invoice institutions for FICO assessments that could be adjusted to reflect increases or decreases attributable to amendments to their prior period call reports. Because FICO assessments are collected in the same manner as FDIC assessments, the FDIC’s billing practices, as agent for FICO, have long included the above-described adjustment provision for the FICO assessments. Thus, FHFA has determined that it would be appropriate, as FICO’s regulator, to adopt a rule to make clear that such adjustments must cease after FICO has collected its final assessment from the insured depository institutions, and that FICO has no obligation to make any adjustments to prior FICO assessments. This rulemaking pertains only to the FICO assessments, which the FDIC collects on behalf of FICO. It does not affect the deposit insurance assessments that the FDIC collects from insured depository institutions, which will continue in their normal manner. The sections below describe the content of the proposed rule.

III. The Proposed Rule

Content of the Proposed Rule. The proposed rule would do four things. First, it would provide that all FICO assessments collected during 2019 will be final, meaning that there will be no possibility of any subsequent adjustments to those assessment amounts. Second, it would provide that after the collection of the final FICO assessment (which is expected to occur on March 29, 2019) no insured depository institution would be entitled to any adjustment of any prior FICO assessment that arises as a result of an amendment to the call report on which the prior assessment had been based. This recognizes the fact that adjustments to prior FICO assessments can only be made as part of the process of collecting a subsequent FICO assessment. Third, it would preserve the existing adjustment practice through the final FICO assessment collection, i.e., it would allow the FDIC, as agent for FICO, to adjust the March 2019 FICO assessment for any institution to reflect amendments that the institution has made to its call reports for any calendar quarters prior to and including the fourth quarter of 2018. This provision is phrased in terms of setting March 26, 2019—the projected date as of which the FDIC will finalize the amounts due for the March 2019 FICO assessment—as the last date for any such call report amendments to affect the institution’s FICO assessments. Fourth, the proposal includes a provision that is intended to address the possibility, which FHFA believes to be small, that FICO may need to conduct another assessment in June 2019, which would occur only if the March collection did not yield sufficient monies to make the remaining interest payments on the FICO bonds. This provision has been drafted to preserve the current practice of allowing an insured depository institution to amend the call report on which its June FICO assessments will be based up until the date on which the FDIC finalizes the amounts due from each institution for that quarter. This paragraph provides that any amendments to the call reports for the calendar quarter ending on March 31, 2019 that are submitted after June 25, 2019, the anticipated date on which the FDIC would finalize payments for the collection, will not affect the institution’s FICO assessment. Any amended call reports for the first quarter of 2019 submitted prior to that date will be used to calculate the June assessments. This is consistent with current practice for FICO assessments, under which payment amounts for FICO assessments are finalized three days prior to the date of collection.

Analysis. In the absence of an ongoing FICO assessment process there is no funding mechanism for FICO to provide an insured depository institution a credit for any overpayment of a prior FICO assessment or to bill it for any underpayment of a prior assessment. FHFA has therefore determined to provide clarity and finality by affirmatively declaring the FICO assessment adjustment practices terminated, effective with the collection

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17 The number of call report amendments submitted during a particular calendar quarter that will affect a FICO assessment will vary, but is small in comparison to the number of insured depository institutions filing call reports with FDIC. Generally speaking, the dollar amounts of the gross FICO refunds and FICO additional collections for any calendar quarter are also small, and the net amounts of such adjustments during a particular quarter often are less than $100,000.

18 Two interest payments, in the approximate amount of $26 million each, are due during March 2019, and FICO will collect monies needed to make those payments during the December 2018 collection. The remaining three interest payments, in the approximate amounts of $25 million each, are due during April, June, and September 2019.
of the final FICO assessment. FHFA is mindful of the statutory requirement that FICO should assess the depository institutions for its costs in the same manner as the FDIC assesses those institutions for deposit insurance purposes. FHFA also understands, however, that the FDIC has an established practice of allowing insured depository institutions to have adjustments made to their prior FDIC assessments if they later amend the call report data on which those assessments were based, provided it occurs within the three-year statutory period, a practice that will not be available when the FICO assessments cease.

A key difference between the FICO assessments and the FDIC assessments is that the FDIC assessments are continual, with no predetermined termination date. The FICO assessment authority, however, is required by statute to cease after FICO has collected sufficient monies to pay the interest and related costs on its Obligations. In light of that difference, FHFA believes that the statutory language requiring FICO to conduct its assessments in the same manner as the FDIC assessments is best read as requiring FICO to follow the FDIC practice for prior period adjustments only for so long as FICO actually is collecting assessments from the insured depository institutions.

FHFA has drafted the proposed regulation in that manner, i.e., the proposed rule would preserve the existing FDIC adjustment process through and including what is expected to be the final collection of the FICO assessment in March 2019. Until that final collection has been completed, all insured depository institutions that are eligible to be credited a refund for any prior overpayment of their FICO assessment or to be billed for any prior underpayment of their FICO assessment will be able to continue to have the appropriate adjustment included in the calculation of the amount they are to pay.

For the foregoing reasons, FHFA does not believe that the “in the same manner” language of the Bank Act can reasonably be construed to require FICO to provide refunds to, or to collect monies from, insured depository institutions that amend a prior period call report after FICO has ceased its assessments. As noted above, there will be no practical way to process such adjustments because there will be no invoiced amount against which a credit could be applied or to which a surcharge could be added. Moreover, there is no source of funds from which FICO could pay cash refunds because FICO will have used all monies received from its prior assessments to pay the interest and other costs due on its Obligations. FICO also could not assess insured depository institutions to obtain funds to provide refunds to other institutions because its authority is limited to assessing the institutions only for monies needed for interest payments, issuance costs, and custodial fees. Finally, Congress has mandated that FHFA dissolve FICO as soon as practicable after it has repaid the last of its Obligations, which evidences an intent that FICO may not undertake any new activities, such as facilitating collections from and payments to insured institutions, after FICO has repaid its Obligations.

FHFA believes that the most appropriate reading of the Bank Act in these circumstances is that it allows insured depository institutions to continue to receive refunds for prior overpayments (and to continue to be billed for prior underpayments) in the same manner as FDIC assessments through and including the final FICO assessment. That approach gives appropriate effect to the “in the same manner” language of the statute without creating any conflict with the provision requiring the prompt dissolution of FICO, and without imposing on FICO any obligations that are not expressly mandated by the Bank Act.

FHFA also does not believe that the proposed rule would have a significant effect on FDIC-insured institutions. As an initial matter, the number of insured depository institutions amending call reports in any calendar quarter that affect their prior FICO assessments typically is small. For example, the number of such amended call reports for the fourth quarter of 2017 was 91, out of approximately 5,600 FDIC-insured depository institutions filing call reports. Moreover, the dollar amount of FICO assessment adjustments also is generally small. For that same period, the gross amount of refunds of prior FICO assessments related to those amended call reports was approximately $24,000, while the gross amount of collections of prior FICO underpayments was approximately $170,000, resulting in a net surplus of collections over refunds of approximately $146,000, i.e., the insured depository institutions generally owe more for underpayments than they are entitled to receive in refunds. From mid-2011 through the last 2017 assessment period, the average net quarterly adjustment of prior FICO assessments resulting from all institutions’ amendments to their prior call reports was approximately $95,000 of additional collections of prior FICO underpayments. As noted previously, and notwithstanding the typically modest numbers involved, the proposed rule has been drafted so as to preserve, through the date of the final FICO collection, the current practice of allowing all insured depository institutions to have their FICO assessments adjusted to reflect amendments to their prior call reports up until the date that FDIC finalizes the amount of each institution’s final FICO assessment in March 2019.

IV. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501 et seq.) requires that regulations involving the collection of information receive clearance from the Office of Management and Budget (OMB). This rule contains no such collection of information requiring OMB approval under the Paperwork Reduction Act. Consequently, no information has been submitted to OMB for review.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a notice of proposed rulemaking, an agency prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the proposed rule on small entities.20 A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic effect on a substantial number of small entities. The SBA has defined “small entities” to include banking organizations with total assets less than or equal to $550 million.21 As discussed further below, the FHFA certifies that this proposed rule would not have a significant impact on a substantial number of FDIC-insured small entities.

Description of Need and Policy Objectives

By statute, FHFA must dissolve FICO as soon as practicable after it has made the final payments of principal and interest due on its Obligations, the last of which matures in September 2019. To facilitate FICO’s prompt and orderly dissolution, and for the other reasons described in Section III, above, FHFA is proposing to make all 2019 FICO assessments final and to terminate FICO assessment adjustments as of March 26, 2019.

20 5 U.S.C. 601 et seq.
21 13 CFR 121.201 (as amended, effective December 2, 2014).
Description of the Proposal

A description of the proposal is presented in Section III: Contents of the Proposed Rule. Please refer to it for further information.

Other Federal Rules

FHFA has exclusive regulatory authority over FICO and has sole responsibility for interpreting and applying the provisions of the Bank Act that govern FICO’s operations. For the reasons described in Section III, above, FHFA has determined that the most appropriate way to interpret the provisions of the Bank Act that refer to the manner in which the FDIC conducts its own assessments is to read them as applying only while FICO is conducting its assessments. FHFA has not identified any likely duplication, overlap, and/or potential conflict between the proposed rule and any other federal rule.

Economic Impacts on Small Entities

The proposed rule would apply to FICO and the manner in which it conducts its assessments, and could indirectly affect any FDIC-insured depository institutions that have been assessed to pay interest on the FICO’s obligations. As of March 2018, the FDIC insured 5,606 depository institutions, of which 4,492 are defined as small banking entities for purposes of the RFA.22 Each insured depository institution’s share of the FICO assessment is based on the insured depository institution’s self-reported call report data, which the depository institution may amend after their initial filing with the FFIEC. Because decisions to amend previously filed call reports are solely within the control of the insured depository institution, it is not possible to predict how many depository institutions may amend a prior period call report during any calendar quarter, how many of those institutions amending a prior call report would be small entities for RFA purposes, whether the call report amendments would affect the calculation of an individual institution’s prior FICO assessment, the dollar amount by which a prior FICO assessment had changed as a result of an amended call report, or the net amount of all such changes for all insured depository institutions, i.e., whether the dollar amount of all refunds for prior overpayments was greater or less than the dollar amount of all billings for prior underpayments. Based on historical FFIEC data relating to call report amendments that affected individual institution FICO assessments, however, it appears that the proposed rule would not affect a substantial number of small entities, and that the economic effect on those small entities that may be affected by the proposed rule would not be significant. Indeed, the potential net economic effect on those small entities would most likely be positive, meaning that more of them would receive a financial benefit—being relieved of the obligation to pay for any prior underpayment of a FICO assessment—than would experience the negative effect of losing refunds for prior overpayment of FICO assessments. Between March 2012 and December 2017, there has been an average of approximately 205 FICO assessments amended per calendar quarter, split evenly between refunds and additional collections. Based on the proportion of small entities to the total number of FDIC-insured depository institutions, FHFA has deemed approximately 80 percent of those amendments to have been attributable to small entities. The actual number of small entities amending call reports that affect their FICO assessments is apt to be lower, however, because each institution may amend multiple quarters’ call reports at one time. For example, an institution amending a call report from a particular calendar quarter two years ago may also amend some or all of the subsequent call reports. Of the 164 FICO assessment amendments attributable to small banking entities per quarter, if each entity submits an average of two amendments per quarter, approximately 82, or slightly less than two percent, of FDIC-insured small banking entities would be affected per quarter by the proposed rule.

During the same period, the average gross FICO refunds to institutions due to their overpayments of prior FICO assessments was approximately $139,000 per quarter, or an average of about $1,350 per amendment. The average gross additional FICO collection for underpayment of prior FICO assessments was $243,000 per quarter, or $2,370 per amendment. Based on those numbers, and assuming the largest possible estimated refunds, i.e., where an institution amended call reports for each of the twelve calendar quarters in the three year period and was entitled to an overpayment credit for each quarter of $1,350 each, the potential cost to that institution would be $16,200. In a similar fashion, assuming the largest possible estimated billings, i.e., where the institution amended its twelve most recent call reports and had underpaid each of the FICO assessments for those periods, the potential savings to that institution would be $28,440. These figures indicate that the proposed rule would likely not have a significant economic effect on even the smallest banking entities. When viewed in the aggregate, it appears that the most likely net effect on all FDIC insured institutions, including small entities, will be positive because the available data indicates that most adjustments to prior FICO assessments result in the depository institution paying additional amounts to make up for prior underpayments of its prior period FICO assessments, and that the amounts of such billings are greater than the amounts of any refunds.

The proposed rule would pose no regulatory costs for FDIC insured small entities, as their FDIC assessment process would remain in place as currently implemented. Overall assessment costs will be permanently reduced to the extent each entity’s FICO assessment is no longer collected. Further, FDIC assessment adjustments would be unaffected by the proposed rule, which typically represent 90 percent of an insured institution’s total potential adjustment value. For these reasons and based on the figures cited above, FHFA finds that the proposed rule would not have a significant economic impact on a substantial number of small entities.

Alternatives Considered

As discussed previously, FHFA is issuing the proposed rule to provide clarity and finality to an issue—the status of future adjustments to prior FICO assessments—that is not otherwise addressed by the statute. FHFA has considered three other approaches to addressing this issue. First, FHFA considered taking no action. That approach likely would have resulted in insured depository institutions being in the same situation as will be the case under the proposed rule—without any mechanism to process adjustments to their prior FICO assessments—but neither they nor FICO would have had any guidance as to the status of their prior FICO assessments. By providing that all FICO assessments become final and nonrefundable when FICO completes its 2019 assessments, the proposed rule provides certainty to those institutions that they would not have otherwise, and without placing them in any different situation than would be the case if FHFA took no action.

Second, FHFA considered whether, once all FICO obligations are paid, FICO could assess all FDIC-insured institutions or use its own assets to obtain the monies needed to pay refunds to any insured depository

22 Call Report data as of March 31, 2018.
institutions whose FICO assessments had changed due to amendments to their call reports. FHFA concluded that further assessments are not legally permissible because Congress has authorized FICO to assess FDIC-insured institutions only for three specific purposes—to pay interest on the FICO Obligations, issuance costs, and custodian fees—which means that FICO’s assessment authority does not extend to obtaining monies for paying refunds of prior FICO assessments. FICO also could not use its own assets to provide such monies because, as described previously, FICO has no legal obligation under any statute to reimburse insured institutions for their prior overpayments of FICO assessments, and has no authority to spend its assets for any purposes beyond those authorized by statute.

Third, FHFA considered whether FICO could direct the FDIC, as collection agent, to continue to process adjustments to prior FICO assessments on its own, but deemed that approach not to be legally permissible. The FDIC acts as FICO’s agent when collecting the FICO assessments, and as such FDIC’s authority derives from, and can be no greater than, FICO’s own assessment authority.

Solicitation of Comments

FHFA invites comments on all aspects of the supporting information provided in this RFA section.

List of Subjects in 12 CFR Part 1271

Accounting, Community development, Credit, Federal home loan banks, Government securities, Housing, Miscellaneous federal home loan bank operations and authorities, Reporting and recordkeeping requirements.

Authority and Issuance

Accordingly, for reasons stated in the SUPPLEMENTARY INFORMATION, and under the authority of 12 U.S.C. 1431(a), 1432(a), 4511(b), 4513, 4526(a), FHFA proposes to amend part 1271 of subchapter D of chapter XII of title 12 of the Code of Federal Regulations as follows:

PART 1271—MISCELLANEOUS FEDERAL HOME LOAN BANK OPERATIONS AND AUTHORITIES

1. The authority citation for part 1271 continues to read as follows:

Authority: 12 U.S.C. 1430, 1431, 1432, 1441(b)(8), (c), (j), 1442, 4511(b), 4513(a), 4526.

2. Amend §1271.37 by adding paragraph (d)(1) to read as follows:

(d)(1) Final Assessments. All Financing Corporation assessments collected during 2019 shall be final. Subsequent to March 29, 2019, no insured depository institution shall have any right to receive refunds for any overpayment of any prior Financing Corporation assessments nor shall it be billed for any underpayment of any prior Financing Corporation assessments that arise as a result of an amendment to any Consolidated Reports of Condition and Income on which the prior Financing Corporation assessment had been based.

(2) Amendments to call reports. Amendments to an institution’s Consolidated Reports of Condition and Income for quarters prior to and including the fourth quarter of 2018 shall not affect an institution’s Financing Corporation assessments after March 26, 2019.

(3) June 2019 Assessment. In the event Financing Corporation assessments are collected in June 2019, amendments to an institution’s first quarter 2019 Consolidated Reports of Condition and Income that are submitted after June 25, 2019 shall not affect the institution’s Financing Corporation assessment.


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

FOR FURTHER INFORMATION CONTACT:
Michael Hughlett, Aviation Safety Engineer, Rotorcraft Standards Branch, Policy and Innovation Division, FAA, 10101 Hillwood Pkwy., Fort Worth, Texas 76177; telephone (817) 222-5110; email Michael.Hughlett@faa.gov.

SUPPLEMENTARY INFORMATION:
Comments Invited

The FAA invites interested parties to submit comments on the proposed airworthiness standards for the address specified above. Commenters must identify the VAT Model S–52L on all submitted correspondence. The most helpful comments reference a specific portion of the airworthiness standards, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received on or before the closing date before issuing the final acceptance. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change the proposed airworthiness standards based on received comments.

Background

The primary category for aircraft was created specifically for the simple, low performance personal aircraft. Section 21.17(f) provides a means for applicants to propose airworthiness standards for their particular primary category aircraft. The FAA procedure establishing appropriate airworthiness standards includes reviewing and possibly revising the applicants’ proposal, publication of the submittal in the Federal Register for public review and comment, and addressing the comments. After all necessary revisions, the standards are published as approved FAA airworthiness standards.

Proposed Airworthiness Standards for Acceptance Under the Primary Category

This document prescribes airworthiness standards for the issuance of a type certificate for the VAT Model S–52L, a primary category rotorcraft, and its engine. The airworthiness standards for this aircraft include a subset of regulations for the fuel system that are at amendment levels higher than Amendment 27–0 to provide improved occupant protection.
Each person who applies under part 21 for a change to this type certificate must show compliance with these requirements.

**CAR 13 effective 03/5/1952 as follows:**

**CAR 13 effective 05/16/1953 as follows:**

**14 CFR 33 through amendment 33–9 as follows:**
- 33.4, Appendix A33.

**14 CFR 33 through amendment 33–30 as follows:**
- 33.7(b).

**14 CFR 27 through amendment 27–0, except as noted below:**
- 27.1529 at amendment 27–18.
- 27.561 is replaced with VAT.561.
- 27.785 is replaced with VAT.785.

**14 CFR 27 through amendment 27–30 as follows:**
- 27.952(a), 27.952(c), 27.952(f), 27.952(g).

**14 CFR 27 through amendment 27–35 as follows:**
- 27.975(b).

**VAT.561 General:**
- (a) The rotorcraft, although it may be damaged in emergency landing conditions on land or water, must be designed as prescribed in this section to protect the occupants under those conditions.
- (b) The structure must be designed to give each occupant every reasonable chance of escaping serious injury in a minor crash landing when:
  - (1) Proper use is made of seats, belts, and other safety design provisions;
  - (2) The wheels are retracted (where applicable); and
  - (3) The occupant experiences the following ultimate inertia forces relative to the surrounding structure:
    - (i) Upward—1.5g.
    - (ii) Forward—4.0g.
    - (iii) Sideward—2.0g.
    - (iv) Downward—4.0g.
    - (v) Rearward—4.0g.
- (c) The supporting structure must be designed to restrain, under any ultimate inertial load up to those specified in this paragraph, any item of mass above and/or behind the crew and passenger compartment that could injure an occupant if it came loose in an emergency landing. Items of mass to be considered include, but are not limited to, rotors, transmissions, and engines. The items of mass must be restrained for the following ultimate inertial load factors:
  - (1) Upward—1.5g.
  - (2) Forward—4.0g.
  - (3) Sideward—2.0g.
  - (4) Downward—4.0g.

**VAT.785 Seats and berths:**
- (a) The seats and berths, and their supporting structures, must be designed for loads resulting from the specified flight and landing conditions, including the emergency landing conditions of VAT.561.
- (b) The reactions from safety belts and harnesses must be considered.
- (c) Each pilot seat must be designed for the reactions resulting from the application of the pilot forces prescribed in Sec. 27.397.
- (d) The structural analysis and testing of the structures specified in paragraphs (a) through (c) may be simplified—
  - (1) By assuming that the critical load in each direction, as determined from the prescribed flight, ground, and emergency landing conditions, acts separately; or
  - (2) By using selected combinations of loads, if the required strength in the specified directions is proven.
- (e) Each occupant’s seat must have a combined safety belt and shoulder harness with a single-point release. Each pilot’s combined safety belt and shoulder harness must allow each pilot, when seated with safety belt and shoulder harness fastened, to perform all functions necessary for flight operations. There must be a means to secure belts and harnesses, when not in use, to prevent interference with the operation of the rotorcraft and with rapid egress in an emergency.
- (f) Each occupant must be protected from serious head injury by a safety belt plus a shoulder harness that will prevent the head from contacting any injurious object.
- (g) The safety belt and shoulder harness must meet the static strength requirements specified by this rotorcraft type certification basis.

**VAT.963 Fuel tanks: General:**
- Each flexible fuel tank bladder or liner must be approved or shown to be suitable for the particular application and must be puncture-resistant. Puncture resistance must be shown by meeting TSO–C80 paragraph 16.0 requirements using a minimum puncture force of 250 pounds.

**14 CFR 36 through amendment 36–30 as follows:**
- (a) Subpart H

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**


**RIN 2120–AA64**

Airworthiness Directives; CFM International S.A. Turbofan Engines

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

**ACTION:** Notice of proposed rulemaking (NPRM); withdrawal.

**SUMMARY:** The FAA withdraws an NPRM that published on August 25, 2017 regarding an unsafe condition involving certain CFM International CFM56–7B turbofan engines. The agency subsequently determined that the identified unsafe condition was not adequately addressed by the proposed actions and published two final rules that adequately address the identified unsafe condition.

**DATES:** Effective September 26, 2018, the FAA withdraws the NPRM published at 82 FR 40516, on August 25, 2017.

**ADDRESSES:** You may examine the Airworthiness Directive (AD) docket on the internet at http://www.regulations.gov by searching for and locating Docket No. FAA–2017–0313; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this action, the NPRM (82 FR 40516, August 25, 2017) the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is U.S. Department of Transportation, Docket Operations, M 30, West Building Ground Floor, Room W12 140, 1200 New Jersey Avenue SE, Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Christopher McGuire, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington MA, 01803; phone: 781–238–7120; fax: 781–238–7199; email: chris.mcguire@faa.gov.

**SUPPLEMENTARY INFORMATION:**

Issued in Fort Worth, Texas, on September 17, 2018.

Jorge Castillo,

Acting Manager, Rotorcraft Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2018–20873 Filed 9–25–18; 8:45 am]

BILLING CODE 4910–13–P
Discussion
The FAA issued an NPRM proposing to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) with an AD applicable to certain CFM International CFM56–7B turbofan engines. The proposed AD would have required a one-time ultrasonic inspection (USI) or eddy current inspection (ECI) of certain fan blades and, if they fail the inspection, their replacement with parts eligible for installation. The proposed action was prompted by a report of an in-flight fan blade failure and uncontained forward release of debris on a CFM56–7B turbofan engine.

Since issuing the NPRM, the FAA determined that the identified unsafe condition was not adequately addressed by the actions proposed in the NPRM. Therefore, the FAA published two final rules, AD 2018–09–51 (83 FR 23794, May 23, 2018) and AD 2018–10–11 (83 FR 22836, May 17, 2018) to require initial and repetitive USI or ECI of certain fan blades, and to reduce the compliance time for the inspection of certain fan blades. The unsafe condition identified in the NPRM is now addressed by AD 2018–09–51 (effective June 7, 2018) and AD 2018–10–11 (effective June 1, 2018).

The Withdrawal

SUMMARY: The U.S. Department of Labor proposes to remove regulations for an inoperative program while continuing to require non-discrimination and equal-employment opportunity under its programs. The Department is undergoing a process of identifying regulations that are “outdated” and “unnecessary.” The regulations to be rescinded by the proposed rule are “outdated” because they administer a program that no longer exists. And they are “unnecessary” because they currently serve no purpose, as their existence or non-existence has no impact on the Department’s enforcement of non-discrimination standards under its existing programs. In particular, the Department proposes to rescind its regulations implementing Section 167 of the Job Training Partnership Act of 1982, as amended (JTPA). Section 167 contained the nondiscrimination and equal-opportunity provisions of the JTPA. In 1998, Congress passed the Workforce Investment Act (WIA), which repealed the JTPA and required the Secretary of Labor to transition any authority under the JTPA to the system that WIA created. WIA, in turn, was subsequently altered by the Workforce Innovation and Opportunity Act (WIOA). In sum, the proposed rule removes regulations for an inoperative program, but has no impact on existing non-discrimination rules.

DATES: To be assured of consideration, comments must be received on or before October 26, 2018.

ADDRESSES: Comments may be submitted, identified by Regulatory Information Number (RIN) 1290–AA32, by any one of the following methods:
• Fax: (202) 693–6505 (for comments of six pages or less).
• Mail or Hand Delivery/Courier: Naomi Barry-Perez, Director, Civil Rights Center (CRC), U.S. Department of Labor, 200 Constitution Avenue NW, Room N–4123, Washington, DC 20210. Telephone (202) 693–6500 (VOICE) or (800) 877–8339 (TTY).

FOR FURTHER INFORMATION CONTACT: Naomi Barry-Perez, Director, Civil Rights Center, U.S. Department of Labor, 200 Constitution Avenue NW, Room N–4123, Washington, DC 20210, telephone (202) 693–6500 (VOICE) or (800) 877–8339 (Federal Relay Service—for TTY), or by email at CRC–WIOA@dol.gov.

SUPPLEMENTARY INFORMATION:
I. Background
Under the JTPA, the Department of Labor provided financial assistance to certain recipients for the purpose of establishing programs to meet the job training needs of youth and adults facing serious barriers to employment. Section 167 of the JTPA contained nondiscrimination and equal opportunity provisions that prohibited discrimination on the grounds of race, color, religion, sex, national origin, age, disability, political affiliation or belief, and for beneficiaries only, citizenship status or participation in a JTPA-funded program or activity.

As amended by the Job Training Reform Amendments of 1992, the JTPA...
provided that final regulations implementing Section 167 be issued within 90 days of the enactment date of the Job Training Reform Amendments of 1992. On January 15, 1993, the Department issued the implementing regulations at 29 CFR part 34 for the nondiscrimination and equal opportunity provisions of the JTPA. The rule applies to recipients of Federal financial assistance under the JTPA. The rule imposes general nondiscrimination and equal opportunity requirements, as well as certain affirmative obligations, such as data collection and recordkeeping requirements.

The JTPA was repealed by the Workforce Investment Act of 1998 (WIA). The Department’s regulations implementing WIA provided for the phased transition of the JTPA programs to WIA, to be fully completed by July 1, 2000. Section 188 of WIA contained substantially similar nondiscrimination and equal opportunity requirements as those contained in the JTPA. The Department issued regulations implementing WIA Section 188 at 29 CFR part 37 on November 12, 1999. WIA in turn was superseded by the Workforce Innovation and Opportunity Act (WIOA) in 2014. Section 188 of WIOA contains the same nondiscrimination and equal opportunity provisions as those in WIA. The Department issued final regulations implementing WIOA Section 188 at 29 CFR part 38 on December 2, 2016.

II. Purpose of the Regulatory Action

The purpose of this action is to rescind the regulations implementing the nondiscrimination and equal opportunity provisions of the JTPA. All funding under the JTPA, together with the obligation to comply with the nondiscrimination and equal opportunity requirements of Section 167, has expired. The Section 167 regulations have been superseded by those implementing Section 188 of first WIA, then WIOA. The regulations at 29 CFR part 34 govern a program that has not been in operation for more than a decade and so are outdated and unnecessary. Therefore, the rescission of the regulations is ministerial in nature. However, the Department wishes to provide the public with the opportunity to submit comments on any aspect of this proposed action.

III. Statement of Legal Authority

Statutory Authority

The Department proposes this rescission consistent with the repeal of the JTPA in Section 199(b)(2) of the Workforce Investment Act of 1998, Public Law 105–220.

Departmental Authorization

CRC issued the regulations implementing the nondiscrimination and equal opportunity obligations of the JTPA pursuant to Secretary’s Order 2–81, 50 FR 28853 (July 16, 1985), which authorized the Assistant Secretary for Administration and Management (OASAM), working through the Director, Office of Civil Rights (OCR), now CRC, to establish and formulate all policies, standards, and procedures, as well as to issue rules and regulations, governing the civil rights enforcement programs under grant-related nondiscrimination statutes. Secretary’s Order 2–85 similarly delegated to OASAM, working through the Director, OCR, now CRC, exclusive authority for the implementation and enforcement of the nondiscrimination and equal opportunity provisions of the JTPA. Secretary’s Orders 2–81 and 2–85 were canceled following the repeal of the JTPA. Secretary’s Order 04–2000, 65 FR 69184 (Nov. 15, 2000), re-delegated the relevant responsibilities to OCR. The delegation in Secretary’s Order 04–2000 covers CRC’s proposed rescission of the regulations implementing the nondiscrimination and equal opportunity provisions of the JTPA.

IV. Rulemaking Analyses and Notices

A. Administrative Procedure Act and Companion Direct Final Rulemaking

Direct final rulemaking in this instance is appropriate because the action is solely ministerial in nature, the underlying statute (Section 167 of the JTPA) has been superseded by the requirements of Section 188 of WIA and WIOA, and all funding under the JTPA has expired. Direct final rulemaking is used when a rule is noncontroversial and is expected to elicit no adverse comment. Here, direct final rulemaking is appropriate because the rule does nothing more than remove regulations for a program that is no longer operative. Under this circumstance, the use of direct final rulemaking satisfies APA requirements.

The Department is publishing concurrently with this proposed rule an identical direct final rule in the rules section of this issue of the Federal Register. This companion proposed rule provides the procedural framework to finalize the rule in the event that any significant adverse comment is received. The comment period for this proposed rule runs concurrently with the comment period for the direct final rule. Any comments received in response to this proposed rule will also be considered as comments regarding the companion direct final rule.

If any significant adverse comments are received during the comment period, the Department will withdraw the direct final rule and proceed in developing a final rule using the usual notice-and-comment procedure. If no significant adverse comment is received during the comment period, the Department will publish a document withdrawing this proposed rule.

B. Executive Orders 12866, 13563, and 13771

This proposed rule is not a “significant regulatory action” within the meaning of Executive Order 12866 and the principles reaffirmed in Executive Order 13563. In addition, this rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

C. Paperwork Reduction Act

This regulatory action will not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

D. Executive Order 13132 (Federalism)

The Department has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have federalism implications. This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

E. Unfunded Mandates Reform Act of 1995

This proposed rule does not contain a Federal mandate that will result in the expenditure by State, local, and tribal governments, in aggregate, or by the private sector of $100 million or more in any one year.

F. Assessment of Federal Regulations and Policies on Families

This proposed rule will not affect family well-being within the meaning of Section 654 of the Treasury and General Government Appropriations Act 1999, 5 U.S.C. 601 note.

G. Regulatory Flexibility Act of 1980

Pursuant to Section 605(b) of the Regulatory Flexibility Act, CRC certifies that this rule will not have a significant economic impact on a substantial...
number of small entities. See 5 U.S.C. 605(b). As explained above, this rule is ministerial in nature and does not impose any additional regulatory burdens.

H. Small Business Regulatory Enforcement Fairness Act of 1996

This proposed rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This proposed rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based companies to compete with foreign-based companies in domestic and export markets.

I. Executive Order 13175 (Indian Tribal Governments)

This proposed rule does not have tribal implications under Executive Order 13175 that would require a tribal summary impact statement. The proposed rule would not have substantial direct effects 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.

J. Executive Order 12630 (Government Actions and Interference With Constitutionally Protected Property Rights)

This NPRM is not subject to Executive Order 12630 because it does not involve implementation of a policy that has takings implications or that could impose limitations on private property use.

K. Executive Order 12988 (Civil Justice Reform)

The NPRM was drafted and reviewed in accordance with Executive Order 12988 and will not unduly burden the Federal court system. The NPRM was: (1) Reviewed to eliminate drafting errors and ambiguities; (2) written to minimize litigation; and (3) written to provide a clear legal standard for affected conduct and to promote burden reduction.

List of Subjects in 29 CFR Part 34

Implementation of the Nondiscrimination and Equal Opportunity Requirements of the Job Training Partnership Act of 1982, as Amended (JTPA).

For the reasons set forth in the preamble, the Department proposes to rescind 29 CFR part 34 in its entirety as follows:

PART 34—[REMOVED AND RESERVED]

1. Remove and reserve part 34, consisting of §§ 34.1 through 34.53.

Signed at Washington, DC, on September 13, 2018.

Bryan Slater,
Assistant Secretary, Office of the Assistant Secretary for Administration and Management, Department of Labor.

BILLING CODE P

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

29 CFR Part 2200

Revisions to Procedural Rules Governing Practice Before the Occupational Safety and Health Review Commission

AGENCY: Occupational Safety and Health Review Commission.

ACTION: Advance notice of proposed rulemaking; extension of comment period.

SUMMARY: On September 7, 2018, the Occupational Safety and Health Review Commission solicited recommendations for amendments to the Commission’s rules of procedure. The comment period, which was set to expire on October 9, 2018, has been extended to November 16, 2018.

DATES: The comment period for the advance notice of proposed rulemaking (83 FR 45366) is extended. Submit comments on or before November 16, 2018.

ADDRESSES: You may submit comments by any of the following methods:

• Email: rbailey@oshrc.gov. Include “Advance notice of proposed rulemaking, 29 CFR part 2200” in the subject line of the message.

• Fax: 202–606–5417.

• Mail: One Lafayette Centre, 1120 20th Street NW, Ninth Floor, Washington, DC 20036–3457.

• Hand Delivery/Courier: same as mailing address.

Instructions: All submissions must include your name, return address, and email address, if applicable. Please clearly label submissions as “Advance notice of proposed rulemaking, 29 CFR part 2200.”

FOR FURTHER INFORMATION CONTACT: Ron Bailey, via telephone at 202–606–5410, or via email at rbailey@oshrc.gov.

SUPPLEMENTARY INFORMATION:

A request was received by the Commission asking that the comment period for the advance notice of proposed rulemaking (ANPRM) be extended to allow “extra time...to coordinate a response to the [notice] among various labor unions and employee advocacy groups.” To make the ANPRM comment process as inclusive as possible, the Commission has extended the comment period for the ANPRM (83 FR 45366) to November 16, 2018.

Dated: September 18, 2018.

Heather L. MacDougall, Chairman.

[FR Doc. 2018–20859 Filed 9–25–18; 8:45 am]
BILLING CODE 7600–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 85 and 86

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Parts 523, 531, 533, 536, and 537


RIN 2127–AL76; RIN 2060–AU09

The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks; Extension of Comment Period

AGENCY: Environmental Protection Agency and National Highway Traffic Safety Administration.

ACTION: Proposed rule; extension of comment period.

SUMMARY: This document extends the comment period for a proposed rule published in the August 24, 2018 issue of the Federal Register entitled The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks and also extends the comment period for NHTSA’s Draft Environmental Impact Statement that accompanies it. This extension is shorter than that requested by several parties, and those requests are accordingly denied.

DATES: The comment period for the proposed rule published August 24, 2018, at 83 FR 42986, is extended. The comment period for the Draft Environmental Impact Statement accompanying that proposed rule and
published on NHTSA’s website is also extended. Comments on both documents should be received on or before October 26, 2018.

**ADDRESSES:** You may send comments, identified by Docket No. EPA–HQ–OAR–2018–0283 and/or NHTSA–2018–0067, by any of the following methods:

- Fax: EPA: (202) 566–9744; NHTSA: (202) 493–2251.
- Mail:  
  - EPA: Environmental Protection Agency, EPA Docket Center (EPA/DC), Air and Radiation Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. Attention Docket ID No. EPA–HQ–OAR–2018–0283. Such deliveries are only accepted between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.
  - NHTSA: West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

InSTRUCTIONS: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to [http://www.regulations.gov](http://www.regulations.gov), including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the “Public Participation” heading of the proposed rule (83 FR at 43470).

**Docket:** For access to the docket to read background documents or comments received, go to [http://www.regulations.gov](http://www.regulations.gov) and/or:

- For EPA: EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20590.
- For NHTSA: Docket Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

- Hand Delivery:
  - EPA: Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Avenue NW, Washington, DC 20460. 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.
  - NHTSA: Docket Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, Rm. W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Management Facility is open between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:**

EPA: Christopher Lieske, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: (734) 214–4584; fax number: (734) 214–4816; email address: lieske.christopher@epa.gov, or contact the Assessment and Standards Division, email address: otaqpublicweb@epa.gov.


**SUPPLEMENTARY INFORMATION:** On August 24, 2018, NHTSA and EPA published in the Federal Register a document titled “The Safer Affordable Fuel-Efficient (SAFE) Vehicles Rule for Model Years 2021–2026 Passenger Cars and Light Trucks.” 83 FR 42986. The public comment period for the proposed rule was scheduled to end on October 23, 2018. Additionally, the public comment period for NHTSA’s DEIS was scheduled to end on September 24, 2018. Eighteen requests to extend the comment period have been received by the agencies’ docket as of the time of this writing, as follows:

<table>
<thead>
<tr>
<th>Requester</th>
<th>Date submitted</th>
<th>Docket ID No.</th>
<th>Length of extension requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental Law and Policy Center ...</td>
<td>August 30, 2018 ....</td>
<td>NHTSA–2018–0067–2738; OAR–2018–0283–0892.</td>
<td>120 days for comment period as a whole.</td>
</tr>
<tr>
<td>Minnesota Pollution Control Agency and Minnesota Department of Transportation.</td>
<td>September 5, 2018</td>
<td>NHTSA–2018–0067–3400; OAR–2018–0283–0872.</td>
<td>120 days for comment period as a whole.</td>
</tr>
<tr>
<td>Requester</td>
<td>Date submitted</td>
<td>Docket ID No.</td>
<td>Length of extension requested</td>
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<tr>
<td>National Governors Association (NGA), Environmental Council of the States (ECOS), National Association of Clean Air Agencies (NACAA), Association of Air Pollution Control Agencies (AAPCA), National Association of State Energy Officials (NASEO), Georgetown Climate Center</td>
<td>September 5, 2018</td>
<td>EPA–HQ–OAR–2018–0283–0871</td>
<td>120 days for comment period as a whole</td>
</tr>
<tr>
<td>Alliance of Automobile Manufacturers (Alliance)</td>
<td>September 6, 2018</td>
<td>NHTSA–2018–0067–3610; OAR–2018–0283–0873</td>
<td>At least 120 day comment period.</td>
</tr>
<tr>
<td>32 U.S. Senators</td>
<td>September 10, 2018</td>
<td>Received by mail</td>
<td>120 days for a comment period as a whole.</td>
</tr>
<tr>
<td>New York Department of Environmental Conservation</td>
<td>September 10, 2018</td>
<td>Received by mail</td>
<td>Not less than 120 day comment period.</td>
</tr>
<tr>
<td>South Coast Air Quality Management District (SCAQMD)</td>
<td>September 12, 2018</td>
<td>EPA–HQ–OAR–2018–0283–0885</td>
<td>120 days for a comment period as a whole.</td>
</tr>
<tr>
<td>Edison Electric Institute (EEI), National Rural Electric Cooperative Association (NRECA), National Association of Manufacturers (NAM), Electric Drive Transportation Association (EDTA), and American Public Power Association (APPA)</td>
<td>September 18, 2018</td>
<td>Received by mail</td>
<td>At least 120 days as a whole.</td>
</tr>
<tr>
<td>New York University School of Law Institute for Policy Integrity</td>
<td>September 19, 2018</td>
<td>Received by mail</td>
<td>At least 120 day comment period.</td>
</tr>
<tr>
<td>Alliance to Save Energy</td>
<td>September 18, 2018</td>
<td>Received by mail</td>
<td>At least 120 days as a whole.</td>
</tr>
<tr>
<td>Alliance to Save Energy</td>
<td>September 19, 2018</td>
<td>Received by mail</td>
<td>At least 120 day comment period.</td>
</tr>
</tbody>
</table>

Many of these requesters also asked that the agencies hold additional public hearings to allow more opportunities for oral presentation of public comments, in additional locations. Specifically:

- NESCIOIUM requested a public hearing be held in a central location in a Northeast state that has adopted California’s greenhouse gas (GHG) standards and zero emissions vehicle (ZEV) program for light-duty vehicles and ZEV, such as Hartford, CT or Boston, MA;
- The Attorneys General requested that EPA (alone or with NHTSA) hold an additional hearing in Sacramento specifically on the California waiver withdrawal proposal, as well as holding additional hearings on the proposal in Los Angeles, Washington, DC, either Portland, OR or Seattle, WA, somewhere in New York State, and Baltimore, MD;
- Georgetown Climate Center also requested that a public hearing be held in Sacramento specifically on the California waiver withdrawal proposal, as well as holding hearings in Los Angeles and Washington, DC, and in other states that have adopted California’s vehicle standards;
- The City of Los Angeles requested that a public hearing be held in Los Angeles, and supported the requests from other parties to hold additional hearings elsewhere around the country;
- The Minnesota Pollution Control Agency and Minnesota Department of Transportation requested that the agencies provide workshops like EPA did during development of the Clean Power Plan rule to help states and other stakeholders understand and comment on the content of the proposal and the agencies’ modeling and analyses; and
- SCAQMD supported the requests from other parties to hold additional hearings.

A separate request to hold a public hearing in Oregon was submitted by the Democratic members of the U.S. Congressional Delegation from Oregon. This request did not include a request for an extension of the comment period.

In addition to requesting extension to the comment period on the proposal, the Attorneys General, the 32 U.S. Senators, the Alliance, ELPC, the Minnesota Pollution Control Agency, Consumer Federation of America, NCAT, CBD et al., SCAQMD, and New York University School of Law’s Institute for Policy Integrity also requested extensions of the comment period for NHTSA’s DEIS, to align the end of that comment period with the (extended) comment period for the proposal.

In support of their requests for longer comment periods and additional public hearings (for those who requested them), all requesters cited the breadth and depth of the record to review, the changes from prior analyses conducted on the same topic, and the importance of the proposal in terms of its potential effects on the U.S. economy, safety, health, and the environment. Several requesters also stated that EPA had provided a 120-day comment period for its Clean Power Plan rule.

The requests for extension of the comment period for the proposal to 120 days (or 180 days, in the case of the

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1 Kamala D. Harris (D, CA); Dianne Feinstein (D, CA); Charles E. Schumer (D, NY); Edward J. Markey (D, MA); Sheldon Whitehouse (D, RI); Jeffrey A. Merkley (D, OR); Richard Blumenthal (D, CT); Patrick Leahy (D, VT); Chris Van Hollen (D, MD); Ron Wyden (D, OR); Catherine Cortez Masto (D, NV); Tina Smith (D, MN); Richard J. Durbin (D, IL); Mazie K. Hirono (D, HI); Benjamin L. Cardin (D, MD); Michael F. Bennet (D, CO); Jeanne Shaheen (D, NH); Margaret Wood Hassan (D, NH); Maria Cantwell (D, WA); Tammy Duckworth (D, IL); Cory A. Booker (D, NJ); Tammy Baldwin (D, WI); Jack Reed (D, RI); Patty Murray (D, WA); Kirsten Gillibrand (D, NY); Bernard Sanders (D, VT); Elizabeth Warren (D, MA); Thomas R. Carper (D, DE); Robert Menendez (D, NJ); Christopher A. Coons (D, DE); Bill Nelson (D, FL); Amy Klobuchar (D, MN).


Minnesota requesters) and for additional public hearing locations are denied. Automakers will need maximum lead time to respond to the final rule, and extending the comment period and holding additional public hearings (which would also cause the comment period to be extended) are inconsistent with provision of maximum lead time. We recognize, however, that the original schedule for the proposed rule public comment period did not reflect the Clean Air Act requirement that the record of proceedings allowing oral presentation of data, views, and arguments on a proposed rule be kept open for thirty days after completion of the proceeding to provide an opportunity for submission of rebuttal and supplementary information. 42 U.S.C. 7607(d)(5). Because the final “proceeding allowing oral presentation of data, views, and arguments,” is expected to be the September 26, 2018 public hearing in Pittsburgh, Pennsylvania, the comment period for the proposed rule is being extended by 3 days to Friday, October 26, 2018. To provide additional flexibility to commenters, NHTSA is also extending the public comment period for the DEIS by 32 days to Friday, October 26, 2018. The agencies believe that this amount of time should be adequate for commenters to comment meaningfully on the proposal and on NHTSA’s DEIS.

Issued on September 21, 2018 in Washington, DC, under authority delegated in 49 CFR 1.95 and 501.5

Heidi R. King,
Deputy Administrator, National Highway Traffic Safety Administration.


William L. Wehrum,
Assistant Administrator for Air and Radiation, Environmental Protection Agency.

Tips for Preparing Your Comments.

• Identify the rulemaking by docket number and other identifying information (subject heading, Federal Register date and page number).
• Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) Part or section number.
• Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
• Describe any assumptions and provide any technical information and/or data that you used.
• If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
• Provide specific examples to illustrate your concerns, and suggest alternatives.
• Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
• Make sure to submit your comments by the comment period deadline identified.

II. Background

The Agency’s policy on scientific integrity was based on a Presidential Memorandum for the Heads of Executive Departments and Agencies, Subject Line: Scientific Integrity, Dated: March 9, 2009. The memo directs the Director of the Office of Science and Technology Policy (OSTP) to work with the Office of Management and Budget (OMB) and agencies to develop policies to ensure all scientific work developed and used by the Government is done so with scientific integrity. This proposed rule requires the Contractor to ensure that all personnel within its organization, subcontractors and consultants, that perform, communicate, or supervise scientific activities or use scientific information to perform advisory and assistance services under the specified contract, have read and understand their compliance responsibilities regarding the EPA’s Scientific Integrity Policy.

Environmental Protection Agency


Environmental Protection Agency Acquisition Regulation (EPAAR); Scientific Integrity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is issuing a proposed rule to address scientific integrity requirements in the creation of a contract clause for inclusion in solicitations and contracts when the contractor may be required to perform, communicate, or supervise scientific activities or use scientific information to perform advisory and assistance services. This clause will complement the EPA scientific integrity policy to ensure all scientific work developed and used by the Government is accomplished with scientific integrity.

DATES: Comments must be received on or before November 26, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OARM–2015–0657; FRL–9936–63–OARM, at https://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit: http://www2.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT: Holly Hubbell, Policy, Training, and Oversight Division, Acquisition Policy and Training Service Center (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–564–1091; email address: hubbell.holly@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

1. Submitting Classified Business Information. Do not submit CBI to EPA website https://www.regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI, and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for Preparing Your Comments. When submitting comments, remember to:

• Identify the rulemaking by docket number and other identifying information (subject heading, Federal Register date and page number).

• Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) Part or section number.

• Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.

• Describe any assumptions and provide any technical information and/or data that you used.

• If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

• Provide specific examples to illustrate your concerns, and suggest alternatives.

• Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

• Make sure to submit your comments by the comment period deadline identified.
III. Proposed Rule


1. EPAAR § 1503.1070 explains the basis for the section.

2. EPAAR § 1503.1071 establishes the prescription for use of EPAAR clause 1552.203–72 in all solicitations and contracts when the Contractor may be required to perform, communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services.

3. EPAAR § 1552.203–72—Scientific Integrity clause states the applicability, term definitions as used in this clause, compliance requirements, reporting requirements, if a loss of scientific integrity is detected, and potential remedies.

IV. Statutory and Executive Order Reviews

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

This action is not a “significant regulatory action” under the terms of Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the E.O.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute; unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impact of this final rule on small entities, “small entity” is defined as: (1) A small business that meets the definition of a small business found in the Small Business Act and codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. After considering the economic impacts of this rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, because the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives “which minimize any significant economic impact of the proposed rule on small entities” 5 U.S.C. 503 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. This action establishes a new EPAAR clause that will not have a significant economic impact on a substantial number of small entities. We continue to be interested in the potential impacts of the rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, Local, and Tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of the Title II of the UMRA) for State, Local, and Tribal governments or the private sector. The rule imposes no enforceable duty on any State, Local or Tribal governments or the private sector. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by State and Local officials in the development of regulatory policies that have federalism implications. “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” This rule does not have tribal implications as specified in Executive Order 13175.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045, entitled “Protection of Children from Environmental Health and Safety Risks” (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be economically significant as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that may have a proportionate effect on children. This rule is not subject to E.O. 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because it does not involve decisions on environment health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use” (66 FR 28335 [May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995 (NTTAA)

Section 12(d) [15 U.S.C. 272 note] of the National Technology Transfer and
Advancement Act of 1995, Public Law 104–113, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment in the general public.

K. Congressional Review Act

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 major 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. Section 804(2) defines a “major rule” as any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in (1) an annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. EPA is not required to submit a rule report regarding this action under section 801 as this is not a major rule by definition.

List of Subjects in 48 CFR Parts 1503 and 1552

Environmental protection, Government procurement.

Kimberly Patrick, Director, Office of Acquisition Management.

For the reasons stated in the preamble, 48 CFR parts 1503 and 1552 are proposed to be amended as set forth below:

PART 1503—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTERESTS

1. The authority citation for part 1503 contains the following clause:


2. Add § 1503.1070 to read as follows:

§ 1503.1070 Scientific integrity.

The EPA’s policy on scientific integrity was based on a Presidential Memorandum for the Heads of Executive Departments and Agencies, Subject Line: Scientific Integrity, Dated: March 9, 2009. The memo directs the Director of the Office of Science and Technology Policy (OSTP) to work with the Office of Management and Budget (OMB) and agencies to develop policies to ensure all scientific work developed and used by the Government is done with scientific integrity. This section and clause complement the EPA Scientific Integrity Policy.

3. Add § 1503.1071 to read as follows:

§ 1503.1071 Contract clause.

Contracting Officers shall insert the contract clause at 5152.203–72—Scientific Integrity, in solicitations and contracts when the Contractor may be required to perform, communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services. When performing, communicating, supervising, or utilizing scientific activities or scientific information, the Contractor shall adhere to EPA’s Scientific Integrity Policy.

(a) The authority citation for part 1552 continues to read as follows:


(b) Add § 1552.203–72 to read as follows:

§ 1552.203–72 Scientific integrity.

As prescribed in 1503.1071, the following clause:

Scientific Integrity (Date)

(a) Applicability. This contract will require the Contractor to perform, communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services. When performing, communicating, supervising, or utilizing scientific activities or scientific information, the Contractor shall adhere to EPA’s Scientific Integrity Policy.

(b) Definitions. “Advisory and assistance services” (see FAR 2.101).

“Scientific Activities” means those activities leading to the systematic knowledge of the physical or material world, largely consisting of observation and experimentation. It also includes the supervision, utilization, and communication of these activities.

“Scientific Information” means factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge, such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks on a web page to information that others disseminate. This definition excludes opinions, where the agency’s presentation makes clear that an individual’s opinion, rather than a statement of fact or of the agency’s findings and conclusions, is being offered.

“Scientific Integrity” means the adherence to professional values and practices, that is, the codes of ethics and behaviors in the scientists’ fields of study, when conducting, supervising, communicating, and utilizing the results of science and scholarship. It ensures objectivity, clarity, reproducibility, and utility. It also provides insulation from bias, fabrication, falsification, plagiarism, improper outside interference, and censorship.

(c) Compliance with policy. Prior to beginning performance under this contract, the Contractor shall ensure that all personnel within their organization, including subcontractors and consultants, that perform,
communicate, or supervise scientific activities, or use scientific information to perform advisory and assistance services under this contract, have read and understand their compliance responsibilities with EPA’s Scientific Integrity Policy. This requirement applies to any personnel that will supervise, conduct, utilize, or communicate scientific activities or scientific information. Examples of such scientific activities include, but are not limited to, computer modelling, economic analysis, field sampling, laboratory experimentation, demonstrating new technology, statistical analysis, and writing a review article on a scientific issue.

(1) Consistent with the objective of promoting a culture of scientific integrity and transparency, as discussed in EPA’s Scientific Integrity Policy, the Contractor agrees to:

(i) Produce scientific products of the highest quality, rigor, and objectivity, by adhering to applicable EPA information quality policy, quality assurance policy, and peer review policy;

(ii) Prohibit the suppression, alteration, or otherwise impede the timely release of scientific findings or conclusions;

(iii) Adhere to the Peer Review Handbook, current edition, for the peer review of scientific and technical work products generated through this contract;

(iv) Act honestly and refrain from acts of research misconduct, including publication or reporting, as described in EPA Order 3120.5 Policy and Procedures for Addressing Research Misconduct. Research misconduct does not include honest error or differences of opinion;

(v) Require that reviews of the content of a scientific product be based only on scientific quality considerations, e.g., the methods used are clear and appropriate, the presentation of results and conclusions is impartial;

(vi) Ensure scientific findings are generated and disseminated in a timely and transparent manner, including scientific research performed by subcontractors and consultants who assist with developing or applying the results of scientific activities;

(vii) Include an explication of underlying assumptions, accurate contextualization of uncertainties, and a description of the probabilities associated with both optimistic and pessimistic projections when communicating scientific findings, if applicable;

(viii) Document the use of independent validation of scientific methods;

(ix) Document any independent review of the Contractor’s scientific facilities and testing activities, as occurs with accreditation by a nationally or internationally recognized sanctioning body; and

(x) Make scientific information available online in open formats in a timely manner, including access to data and non-proprietary models.

(2) To assure protection of staff supported by this contract, consistent with the objectives described in the Scientific Integrity Policy, the Contractor agrees to:

(i) Prohibit intimidation or coercion of scientists to alter scientific data, findings, or professional opinions or non-scientific influence of scientific advisory boards. In addition, employees, subcontractors, and consultants, including scientists, managers, and other leadership, shall not knowingly misrepresent, exaggerate, or downplay areas of scientific uncertainty; and

(ii) Prohibit retaliation or other punitive actions toward employees who uncover or report allegations of scientific and research misconduct, or who express a differing scientific opinion. Employees who have allegedly engaged in scientific or research misconduct shall be afforded the due process protections provided by law, regulation, and applicable collective bargaining agreements, prior to any action. The Contractor shall ensure that all employees, subcontractors, and consultants shall be familiar with these protections and avoid the appearance of retaliatory actions.

(e) Loss of scientific integrity. If during performance of this contract the Contractor becomes aware of an actual or potential loss of scientific integrity, the Contractor shall immediately inform the Contracting Officer and Contracting Officer’s Representative with a description of the issue and any corrective action the contractor will take to mitigate the issue. The Contracting Officer and Contracting Officer’s Representative will consult with the Agency’s Scientific Integrity Official on all issues related to the loss of scientific integrity under this contract. The Agency’s Scientific Integrity Official will advise the Contracting Officer and Contracting Officer’s Representative on the appropriate remedy for any actual or potential loss of scientific integrity. The Contractor bears the primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with its own institution. However, EPA retains the ultimate oversight authority for EPA-supported research. The Contractor shall take the actions required as described in EPA Order 3120.5 Policy and Procedures for Addressing Research Misconduct when research misconduct is suspected or found.

(f) Remedies. The Contracting Officer will make the final decision on any remedy to an actual or potential loss of scientific integrity. Potential remedies include:

(1) Acceptance of the Contractor’s proposed mitigation plan to the scientific integrity issue;

(2) Acceptance of an alternate mitigation plan negotiated by the parties;

(3) Termination for convenience, in whole or in part, if no mitigation plan will adequately resolve the actual or potential loss of scientific integrity; or

(4) Termination for default or cause, in whole or in part, if the Contractor was aware of an actual or potential loss of scientific integrity under this contract and did not disclose it or misrepresented relevant information to the Contracting Officer.

Additionally, the Government may debar the Contractor from Government contracting, or otherwise impede the timely release of scientific findings, findings or conclusions when communicating scientific findings, if applicable;

Potential remedies include:

(1) Acceptance of the Contractor’s proposed mitigation plan to the scientific integrity issue;

(2) Acceptance of an alternate mitigation plan negotiated by the parties;

(3) Termination for convenience, in whole or in part, if no mitigation plan will adequately resolve the actual or potential loss of scientific integrity; or

(4) Termination for default or cause, in whole or in part, if the Contractor was aware of an actual or potential loss of scientific integrity under this contract and did not disclose it or misrepresented relevant information to the Contracting Officer.

Additionally, the Government may debar the Contractor from Government contracting, or pursue other remedies as may be permitted by law or this contract.

(g) Subcontractors and Consultants. The Contractor agrees to insert in any subcontract or consultant agreement placed hereunder which shall conform substantially to the language of this clause, including the paragraph (g), unless otherwise authorized by the Contracting Officer.

(h) Additional resources. For more information about the Scientific Integrity Policy, an introductory video can be accessed at: https://youtu.be/PQJCy8BXXQ8. A training video is available at: https://youtu.be/Zc0T7fooot8.

(End of clause)
AGENCY FOR INTERNATIONAL DEVELOPMENT

Board for International Food and Agricultural Development; Notice of Meeting

Pursuant to the Federal Advisory Committee Act, notice is hereby given of the public meeting of the Board for International Food and Agricultural Development (BIFAD). The meeting will be held from 9 a.m. to 12 p.m. CDT on Tuesday, October 16, 2018, at the Downtown Des Moines Marriott Hotel, Davenport and Dubuque Rooms, 700 Grand Avenue, Des Moines Iowa 50309. Participants may attend in person or join via livestream. The link to the global livestream as well as registration information can be found on BIFAD's home page and online at http://www.aplu.org/projects-and-initiatives/international-programs/bifad/bifad-meetings.html.

The central theme of this public meeting will be “Improving Nutrition through Private Sector Engagement Across Food Systems” and will explore how private sector engagement and market system linkages across the food system can help to advance nutrition outcomes. The meeting will help to identify opportunities and challenges for the public and private sectors to work together at different points in the food system to improve the demand, availability, accessibility, and affordability of high-quality diets for vulnerable populations. Discussions will address how to build a business case for private sector involvement in improving diet quality for vulnerable populations and how the public sector can support and incentivize that business case. Recommendations coming out of the meeting will help to inform USAID’s future focus in this area.

The meeting will also include the announcement of the winners of the BIFAD Prize for Scientific Excellence and an update on a BIFAD-commissioned study on the U.S. benefits and capabilities leveraged of USAID investments in developing country agriculture and food security. Following an introduction by Dr. Rob Bertram, Chief Scientist, USAID Bureau for Food Security, a keynote address by Dr. Lawrence Haddad, Executive Director, Global Alliance for Improved Nutrition (GAIN), and framing remarks by Dr. William Masters, Professor, Friedman School of Nutrition Science and Policy at Tufts University, two panels will address: (1) Aspects of the enabling environment that can help accelerate private sector engagement in nutrition and (2) key drivers of private sector engagement to improve diet quality, including aspects of labeling, marketing, standards, and accountability systems. A public comment period is scheduled from 11:30 a.m. to 2:00 p.m. CDT.

For questions about registration, please contact Devin Furguson at dfurguson@aplu.org or (202) 478–6030. For questions about BIFAD, please contact Clara Cohen, Designated Federal Officer for BIFAD in the Bureau for Food Security at USAID. Interested persons may write to her in care of the U.S. Agency for International Development, Ronald Reagan Building, Bureau for Food Security, 1300 Pennsylvania Avenue NW, Washington, DC, 20523–2110 or telephone her at (202) 712–0119.

Clara Cohen,
Designated Federal Officer, Bureau for Food Security, U.S. Agency for International Development.

[FR Doc. 2018–20942 Filed 9–25–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Notice of Request for Extension and Revision of a Currently Approved Information Collection: Advisory Committee and Research and Promotion Background Information

AGENCY: White House Liaison Office, Department of Agriculture.

ACTION: Notice and request for comments.

SUMMARY: This notice announces the U.S. Department of Agriculture’s (USDA) intention to request an extension and a revision to the currently approved Advisory Committee and Research and Promotion Background Information AD–755 Supplemental List—Agricultural Marketing Service Commodity Specific Questionnaire. The revised form will now require applicants to indicate their U.S. citizenship status. The primary objective is to determine the qualifications, suitability, and availability of a candidate to serve on advisory committees and/or research and promotion boards.

DATES: Comments on this notice must be received by November 26, 2018 to be assured of consideration.

ADDRESSES: USDA invites interested persons to submit comments on this notice. Comments may be submitted through one of the following methods:

- Federal eRulemaking Portal: This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to http://www.regulations.gov. Follow the online instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: White House Liaison Office, U.S. Department of Agriculture, 1400 Independence Avenue SW, the Whitten Building, Room 540–A, Washington, DC 20250–3700.

- Hand- or courier-delivered submittals: Deliver to White House Liaison Office, U.S. Department of Agriculture, 1400 Independence Avenue SW, the Whitten Building, Room 540–A, Washington, DC 20250–3700. Instructions: All items submitted by mail or electronic mail must include the agency name and docket number. Comments received in response to this notice will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Cikena Reid, Committee Management Officer, Office of the Secretary, U.S. Department of Agriculture, White House Liaison Office, 1400 Independence Avenue SW, the Whitten Building, Room 540–A, Washington, DC 20250; office phone: (202) 720–2406; email: Cikena.Reid@ossc.usda.gov

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C.
Chapter 35), this notice announces the U.S. Department of Agriculture’s intention to request an extension for and a revision to the Advisory Committee and Research and Promotion Background Information collection form. The primary objective is to determine the qualifications, suitability, and availability of a candidate to serve on advisory committees and/or research and promotion boards.

**Title:** Advisory Committee and Research and Promotion Background Information.

**OMB Number:** 0505–0001.

**Expiration Date of Approval:** September 30, 2018.

**Type of Request:** Extension and Revision of a currently approved information collection document.

**Abstract:** The primary objective is to determine the qualifications, suitability, and availability of a candidate to serve on advisory committees and/or research and promotion boards. The information will be used to both conduct background clearances on the candidates and to compile annual reports regarding membership.

**Estimated Burden:** Public reporting burden for this collection of information is estimated to average 30 minutes per response.

**Respondents:** Individuals.

**Estimated Number of Respondents:** 5,500.

**Estimated Number of Responses per Respondent:** One (1).

**Estimated Total Annual Burden on Respondents:** 5,958.

Comments are invited on: (1) 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) the accuracy of the agency’s estimate of burden 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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by October 26, 2018 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Comments are encouraged to submit their comments to OMB via email to: OIRA_Submission@OMB.EOP.GOV or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

**Animal Plant and Health Inspection Service**

**Title:** Emergency Management Response System (EMRS).

**OMB Control Number:** 0579–0071.

**Summary of Collection:** The Animal Health Protection Act (AHPA) of 2002 is the primary federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease. Through the Foreign Animal Disease Surveillance Program, the Animal and Plant Health Inspection Service (APHIS) Veterinary Services compiles essential epidemiological and diagnostic data that are used to define foreign animal diseases (FAD) and their risk factors. The data is compiled through the Veterinary Services Emergency Management Response System, a web-based database for reporting investigations of suspected FAD occurrences.

**Need and Use of the Information:** APHIS collects information such as the purpose of the diagnostician’s visit to the site, the name and address of the owner/manager and the site, the type of operation being investigated, the number of and type of animals on the premises, vaccination information on the animals in the herd or flock, biosecurity practices at the site, whether any animals have been moved to or from the premises and when this movement occurred, number of sick or dead animals, the results of physical examinations of the affected animals, the results of postmortem examinations, and the number and kinds of samples taken, and the name of the suspected disease.

APHIS uses the collected information to effectively prevent FAD occurrences and protect the health of the United States. Without the information, APHIS has no way to detect and monitor FAD outbreaks in the United States.

**Description of Respondents:** Businesses; and State, Local or Tribal Governments.

**Number of Respondents:** 136.

**Frequency of Responses:** Reporting, on occasion.

**Total Burden Hours:** 1,632.
Animal and Plant Health Inspection Service

Title: Importation of Peppers from Certain Central American Countries.

OMB Control Number: 0579–0274.

Summary of Collection: Under the Plant Protection Act (PPA) (7 U.S.C. 7701–7772), the Secretary of Agriculture is authorized to carry out operations or measures to detect, eradicate, suppress, control, prevent, or retard the spread of plant pests new to the United States or not known to be widely distributed throughout the United States.

Regulations authorized by the PPA concerning the importation of fruits and vegetables into the United States from certain parts of the world are contained in “Subpart Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–72). The fruits and vegetables regulations allow certain type of peppers grown in approved registered production sites in Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama to be imported, under certain conditions, into the United States without treatment while continuing to provide protection against the introduction of quarantine pests into the United States.

Need and Use of the Information: The regulations require the use of information collection activities including inspections by Central American national plant protection organization officials, phytosanitary certificate, labeling of boxes, monitor traps, trapping records, bilateral workplan, production site registrations, quality control program, and emergency action notifications. If the information were not collected, it would cripple the Animal and Plant Health Inspection Service ability to regulate and prevent the importation or spread of plant pests and diseases from entering the United States.

Description of Respondents: Businesses; Federal Government.

Number of Respondents: 36.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 4,285.

Animal and Plant Health Inspection Service

Title: Importation of Peppers from the Republic of Korea.

OMB Control Number: 0579–0282.

Summary of Collection: Under the Plant Protection Act (PPA) (7 U.S.C. 7701–et seq.), the Secretary of Agriculture is authorized to carry out operations or measures to detect, eradicate, suppress, control, prevent, or retard the spread of plant pests new to the United States or not known to be widely distributed throughout the United States. Regulations authorized by the PPA concerning the importation of fruits and vegetables into the United States from certain parts of the world are contained in “Subpart Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–83). The Animal and Plant Health Inspection Service (APHIS) fruits and vegetables regulations allow the importation of peppers from the Republic of Korea under certain conditions into the continental United States.

Need and Use of the Information: The regulations require the use of information collection activities including a phytosanitary certificate and declaration issued by the National Plant Quarantine Service of Korea, greenhouse registrations, inspections, and emergency action notifications. Failing to collect this information would cripple APHIS’ ability to regulate and prevent the importation or spread of plant pests and diseases from entering the United States.

Description of Respondents: Federal Government (Foreign); Business or other for-profit.

Number of Respondents: 2.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 29.

Animal and Plant Health Inspection Service

Title: Movement of Plants and Plant Products from Hawaii and the Territories.

OMB Control Number: 0579–0346.

Summary of Collection: Under the Plant Protection Act (7 U.S.C. 7701), the Secretary of Agriculture is authorized to prohibit or restrict the importation, entry, or movement of fruits, vegetables, plants, and plant pests to prevent the introduction of pests or diseases into the United States, or dissemination of pests and diseases within the United States. The Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ), is responsible for implementing this Act and does so through the enforcement of its Hawaiian and territorial quarantine regulations contained in Part 318 of Title 7, Code of Federal Regulations.

Need and Use of the Information: APHIS will use the following forms and activities to collect information: PPQ 530, PPQ 586, PPQ 519, PPQ 540, Labeling of Boxes for Pest Free Areas, Inspection and Certification, Trapping and Surveillance, Contingency Plans approved by APHIS, Updated Mapping Identifying Places Where Horticultural or Other Crops are Grown, Written Request for Facility Approval—and Recertification, Recordkeeping, Decertification of Pest Free Areas—and Reinstatement, Notification of Emergency Conveyance, Aircraft/Ship Inspections of Departure, Production Site Registration, Packing House Registration, and Box Markings. If APHIS did not collect this information or if APHIS collected this information less frequently, the spread of dangerous plant diseases and pests could cause millions of dollars in damage to U.S. agriculture.

Description of Respondents: Business or other for-profits; State, Local or Tribal Government.

Number of Respondents: 203.

Frequency of Responses: Recordkeeping; Reporting: On occasion.

Total Burden Hours: 8,318.

Animal and Plant Health Inspection Service

Title: Importation of Papayas from Peru.

Control Number: 0579–0410.

Summary of Collection: The Plant Protection Act (PPA, 7 U.S.C. 7701 et seq.) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles within the United States to prevent the introduction of plant pests or their dissemination. The Animal and Plant Health Inspection Service (APHIS) Plant Protection and Quarantine (PPQ) Program enforces the Act by regulating the importation of fruits and vegetables into the United States. These regulations are found in Section 319 of the Code of Federal Regulations (CFR) under “Subpart—Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–81). Under § 319.56–25, papaya fruit from Peru may be imported into the continental United States under certain conditions that prevent the introduction of plant pests into the country.

Need and Use of the Information: APHIS will use information collection activities and actions to ensure these conditions are met. These activities include grower registrations, applications for import permit, notices of arrival, emergency action notifications, and recordkeeping. Also, consignments of fruit must be accompanied by phytosanitary certificates issued by the National Plant Protection Organization (NPPO) of Peru and containing additional declaration stating the provisions of 7 CFR 319.56–25 have been met. These activities for this commodity are the minimum necessary to protect crops and the agriculture industry from dangerous plant pests and diseases.
Description of Respondents: Commercial growers and importers, Foreign Governments.

Number of Respondents: 52

Frequency of Responses: Reporting on occasion, and recordkeeping.

Total Burden Hours: 1,507.

Animal and Plant Health Inspection Service

Title: Importation of Apples from China.

OMB Control Number: 0579–0423.

Summary of Collection: Under the Plant Protection Act (7 U.S.C. 7701, et seq.) the Secretary of Agriculture is authorized to prohibit or restrict the importation, entry, or movement of plants and plant pests to prevent the introduction into the United States or their dissemination within the United States. The regulations in “Subpart—Fruits and Vegetables” (7 CFR 319.56) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests that are new to or not widely distributed within the United States.

Need and Use of the Information: APHIS uses the following information collection activities to prevent the spread of fruit flies and other plant pests from entering into the United States: Operational workplan, production site, and packinghouse registrations, tracking system, box labeling, phytosanitary certificates with declarations, inspections, investigation for detection, handling procedures, and emergency action notification. Failing to collect this information would cripple APHIS’ ability to ensure that apples from China are not carrying plant pests.

Description of Respondents: Business or other for-profit; Federal Government.

Number of Respondents: 196.

Frequency of Responses: Reporting: On occasion; Annually.

Total Burden Hours: 1,117.

Ruth Brown, Departmental Information Collection Clearance Officer.

[FR Doc. 2018–20939 Filed 9–25–18; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Guarantee Fee Rates for Guaranteed Loans for Fiscal Year 2019; Maximum Portion of Guarantee Authority Available for Fiscal Year 2019; Annual Renewal Fee for Fiscal Year 2019

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: This notice helps to improve applicants’ awareness of the Guarantee Fee rates for Guaranteed Loans for fiscal year (FY) 2019, the Maximum Portion of Guarantee Authority Available for FY 2019, and the Annual Renewal Fee for FY 2019 when applying for guaranteed loans under the Business and Industry (B&I) Guaranteed Loan Program.

The Agency has the authority to charge a guarantee fee and an annual renewal fee for loans made under the B&I Guaranteed Loan Program. Pursuant to that authority, and subject to the Continuing Resolution, the Agency is establishing an initial guarantee fee rate of 3 percent and an annual renewal fee rate of one-half of 1 percent for the B&I Guaranteed Loan Program.

The initial guarantee fee is paid at the time the Loan Note Guarantee is issued. The annual renewal fee is paid by the lender to the Agency once a year. Payment of the annual renewal fee is required in order to maintain the enforceability of the guarantee. Additionally, the Agency will require the borrower to have an active System for Award Management (SAM) registration prior to obligation and maintain the active registration until all funds are disbursed.

DATES: Applicability date: September 26, 2018.


SUPPLEMENTARY INFORMATION: As set forth in 7 CFR 4279.120, the Agency has the authority to charge an initial guarantee fee and an annual renewal fee for loans made under the B&I Guaranteed Loan Program. Pursuant to that authority, and subject to the Continuing Resolution, the Agency is establishing an initial guarantee fee rate of 3 percent and an annual renewal fee rate of one-half of 1 percent for the B&I Guaranteed Loan Program. Unless precluded by a subsequent FY 2019 appropriation, these rates will apply to all loans obligated in FY 2019 that are made under the B&I Guaranteed Loan Program. Unless precluded by a subsequent FY 2019 appropriation, these rates will apply to all loans obligated in FY 2019 that are made under the B&I Guaranteed Loan Program. As established in 7 CFR 4279.120(b)(1), the amount of the annual fee on each guaranteed loan will be determined by multiplying the annual fee rate by the outstanding principal loan balance as of December 31, multiplied by the percentage of guarantee.

As set forth in 7 CFR 4279.120(a) and 4279.119(b), each fiscal year, the Agency shall establish a limit on the maximum portion of B&I guarantee authority available for that fiscal year that may be used to guarantee loans with a reduced guarantee fee or guaranteed loans with an increased percentage of guarantee. The Agency has established that not more than 12 percent of the Agency’s apportioned B&I guarantee authority will be reserved for loan guarantee requests with a reduced fee, and not more than 15 percent of the Agency’s apportioned B&I guarantee authority will be reserved for guaranteed loan requests with an increased percentage of guarantee. Once the respective limits are reached, all additional loans will be at the standard fee and guarantee limits.

Allowing a reduced guarantee fee or increased percentage of guarantee on certain B&I guaranteed loans that meet the conditions set forth in 7 CFR 4279.120 and 4279.119 will increase the Agency’s ability to focus guarantee assistance on projects that the Agency has found particularly meritorious. Subject to annual limits set by the Agency in this notice, the Agency may charge a reduced guarantee fee if requested by the lender for loans of $5 million or less when the borrower’s business supports value-added agriculture and results in farmers benefitting financially, promotes access to healthy foods, or is a high impact business development investment located in a rural community that is experiencing long-term population decline; has remained in poverty for the last 30 years; is experiencing trauma as a result of natural disaster; is located in a city or county with an unemployment rate 125 percent of the statewide rate or greater; or is located within the boundaries of a federally recognized Indian tribe’s reservation or within tribal trust lands or within land owned by an Alaska Native Regional or Village Corporation as defined by the Alaska Native Claims Settlement Act. Subject to annual limits set by the Agency in this notice, the Agency may charge an increased percentage of guarantee for high-priority projects or loans where the lender needs the increased percentage of guarantee due to its legal or regulatory lending limit.

As set forth in 2 CFR 25.200(b), each entity that applies and does not have an exemption under 2 CFR 25.110 must be registered in the SAM prior to submitting an application or plan, maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under...
DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board
[B–35–2018]

Foreign-Trade Zone (FTZ)126—Reno, Nevada; Authorization of Production Activity; Tesla, Inc. (Lithium-Ion Batteries, Electric Motors, and Stationary Energy Storage Systems); Sparks and McCarran, Nevada

On May 23, 2018, Tesla, Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 126D, in Sparks and McCarran, Nevada.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the Federal Register inviting public comment (83 FR 25428, June 1, 2018). On September 20, 2018, the applicant was notified of the FTZ Board’s decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board’s regulations, including Section 400.14.


Andrew McGilvray, Executive Secretary.

BILLING CODE 3510–05–P

DEPARTMENT OF COMMERCE

International Trade Administration
[A–570–985]

Xanthan Gum From the People’s Republic of China: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this first sunset review, the Department of Commerce (Commerce) finds that revocation of the antidumping duty order on xanthan gum from the People’s Republic of China (China) would be likely to lead to continuation or recurrence of dumping, at the level indicated in the “Final Results of Sunset Review” section of this notice.

DATES: Applicable September 26, 2018.

FURTHER INFORMATION CONTACT: Magd Zalok or Howard Smith, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4162 or (202) 482–5193, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 19, 2013, Commerce published in the Federal Register the antidumping duty order on xanthan gum from China.1 On June 1, 2018, Commerce published the notice of initiation of this sunset review of the Order, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).2 On June 15, 2018, and June 18, 2018, pursuant to 19 CFR 351.218(d)(3)(i), Commerce received timely and complete notices of intent to participate in the sunset review from domestic producers of xanthan gum, Archer Daniels Midland Company (ADM) and CP Kelco U.S., Inc. (CP Kelco), respectively.3 On July 2, 2018, pursuant to 19 CFR 351.218(d)(3)(i), ADM and CP Kelco filed a timely and adequate substantive response.4 Commerce did not receive a substantive response from any respondent interested party. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(i)(II)(c)(2), we conducted an expedited (120-day) first sunset review of the Order.

Scope of the Order

The product covered by the Order includes dry xanthan gum, whether or not coated or blended with other products. Xanthan gum is included in this order regardless of physical form, including, but not limited to, solutions, slurries, dry powders of any particle size, or unground fiber.

Merchandise covered by the scope of the Order is classified in the Harmonized Tariff Schedule of the United States at subheading 3913.90.20.15. This tariff classification is provided for convenience and

1 See Xanthan Gum from the People’s Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order, 78 FR 43343 (July 19, 2013) (Order).
2 See Initiation of Five-Year (Sunset) Reviews, 83 FR 25436 (June 1, 2018).
customs purposes; however, the written description of the scope is dispositive.  

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, specifically the likelihood of continuation or recurrence of dumping and the magnitude of the margin likely to prevail if the Order were to be revoked, is provided in the accompanying Issues and Decision Memorandum, which is hereby adopted by this notice.  

The Issues and Decision Memorandum is a public document and 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 [http://access.trade.gov](http://access.trade.gov) and in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed at [http://enforcement.trade.gov/frn/](http://enforcement.trade.gov/frn/). The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, we determine that revocation of the Order would likely lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average dumping margins up to 154.07 percent.  

Notification Regarding Administrative Protective Orders

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing the results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.


Christian Marsh,
Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–20844 Filed 9–25–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–066]

Polytetrafluoroethylene Resin From the People’s Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of polytetrafluoroethylene (PTFE) resin from the People’s Republic of China (China) are being, or are likely to be, sold in the United States at less than fair value (LTFV). The final dumping margins of sales at LTFV are listed in the “Final Determination” section of this notice.

DATES: Applicable September 26, 2018.

FOR FURTHER INFORMATION CONTACT: Thomas Schauer or Michael Romani, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0410 and (202) 482–0198, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the Preliminary Determination in the LTFV investigation of PTFE resin from China on May 7, 2018. For a complete description of the events that followed the Preliminary Determination, see the Issues and Decision Memorandum.  

Period of Investigation

The period of investigation is January 1, 2017, through June 30, 2017.

Scope of the Investigation

The product covered by this investigation is PTFE resin from China. For a full description of the scope of this investigation, see the “Scope of the Investigation” in Appendix I of this notice.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by parties in this investigation are addressed in the Issues and Decision Memorandum. A list of issues raised is attached to this notice at Appendix II.

The Issues and Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at [http://access.trade.gov](http://access.trade.gov) and to all parties in Commerce’s Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at [http://enforcement.trade.gov/frn/](http://enforcement.trade.gov/frn/).

Verification

As provided in section 782(i) of the Tariff Act of 1930, as amended (the Act), we verified the U.S. sales and factors of production information submitted by Daikin Fluorochemicals (China) Co., Ltd. (Daikin), and Shandong Dongyue Polymer Material Co., Ltd. (Dongyue) in May 2018 and June 2018. We used standard verification procedures, including an examination of relevant accounting and production records, and original source documents provided by Daikin and Dongyue.


5 For the complete scope language, see “Issues and Decision Memorandum for the Expedited First Conversion to Judicial Protective Orders Concurrently with and hereby adopted by this notice” dated May 22, 2018.

6 See Issues and Decision Memorandum.

China-Wide Entity and Use of Adverse Facts Available

We continue to find that the use of facts available is warranted in determining the rate of the China-wide entity pursuant to section 776(a)(1) and (a)(2)(A)–(C) of the Act. Further, we found that the China-wide entity did not cooperate to the best of its ability to comply with our requests for information and, accordingly, we determined it appropriate to apply adverse inferences in selecting from the facts available, pursuant to section 776(b) of the Act and 19 CFR 351.308(c).

Changes From the Preliminary Determination

Based on our analysis of the comments received and our findings at verification, we made certain changes to our dumping margin calculation for Daikin and Dongyue and revised the margins for non-selected respondents and the China-wide entity to reflect the revised margins for Daikin and Dongyue.5

<table>
<thead>
<tr>
<th>Exporter</th>
<th>Producer</th>
<th>Estimated weighted-average dumping margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daikin Fluorochemicals (China) Co., Ltd</td>
<td>Daikin Fluorochemicals (China) Co., Ltd</td>
<td>91.65</td>
</tr>
<tr>
<td>Shandong Dongyue Polymer Material Co., Ltd</td>
<td>Shandong Dongyue Polymer Material Co., Ltd</td>
<td>54.41</td>
</tr>
<tr>
<td>Hangzhou Fine Fluorotech Co., Ltd</td>
<td>Qingdao Orientalflon New Materials Co., Ltd</td>
<td>77.13</td>
</tr>
<tr>
<td>Shanghai Huayi 3f New Materials Sales Co., Ltd</td>
<td>Zhejiang Juhua Co., Ltd. Fluor-Polymeric Plant</td>
<td>77.13</td>
</tr>
<tr>
<td>China-Wide Entity</td>
<td>Shanghai 3f New Materials Co., Ltd</td>
<td>218.88</td>
</tr>
</tbody>
</table>

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days after public announcement of the final determination or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the Federal Register, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of PTFE resin from China. Commerce determined it appropriate to apply a cash deposit equal to the cash deposit rate applicable to the Chinese exporter/producer combination that supplied that non-Chinese exporter.

Combination Rates

Consistent with Preliminary Determination6 and Policy Bulletin 05.1,7 Commerce calculated combination rates for the respondents that are eligible for a separate rate in this investigation.

Final Determination

Commerce determines that the following weighted-average dumping margins exist:

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of our final affirmative determination of sales at LTFV. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of subject merchandise from China no later than 45 days after our final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all securities posted will be refunded or canceled. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Order

This notice will serve as a reminder to the parties subject to administrative protective order (APO) of their responsibility concerning the disposition of propriety information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

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4 See Preliminary Determination and accompanying Preliminary Decision Memorandum at 14–17.
5 See Issues and Decision Memorandum for a discussion of these changes.
8 See Modification of Regulations Regarding the Practice of Accepting Bonds During the Provisional Measures Period in Antidumping and Countervailing Duty Investigations, 76 FR 61042 (October 3, 2011).
This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act and 19 CFR 351.210(c).


Christian Marsh,
Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I
Scope of the Investigation
The product covered by this investigation is polytetrafluoroethylene (PTFE) resin, including but not limited to granular, dispersion, or coagulated dispersion (also known as micron powder). PTFE resin is covered by the scope of this investigation whether filled or unfilled, whether or not modified, and whether or not containing copolymer additives, pigments, or other materials. Also included is PTFE resin wet raw polymer. The chemical formula for PTFE resin is C2F4, and the Chemical Abstracts Service (CAS) Registry number is 9002–84–0.

PTFE resin further processed into micropowder, having particle size typically ranging from 1 to 25 microns, and a meltflow rate no less than 0.1 gram/10 minutes, is excluded from the scope of this investigation.

PTFE resin is classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 3904.61.0090 and 3904.69.0000. Subject merchandise may also be classified under HTSUS subheading 3904.69.5000. Although the HTSUS subheadings and CAS Number are provided for convenience and Customs purposes, the written description of the scope is dispositive.

Appendix II
List of Topics Discussed in the Issues and Decision Memorandum
I. Summary
II. Background
III. Scope Comments
IV. Surrogate Country
V. Separate Rates
VI. China-Wide Rate
VII. Changes Since the Preliminary Determination
VIII. Discussion of the Issues
   a. Daikin Fluorochemicals (China) Co., Ltd.
      1. Unreported U.S. Sales
      2. Ocean Freight Expenses
      3. Factor of Production of a Certain Input
      4. Surrogate Value for R–22
      5. Surrogate Financial Ratios
   b. Separate Rate Eligibility
IX. Recommendation

DEPARTMENT OF COMMERCE
International Trade Administration
[A–351–845]
Certain Hot-Rolled Steel Flat Products From Brazil: Final Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that certain hot-rolled carbon steel flat products from Brazil are being, or are likely to be, sold at less than normal value during the period of review (POR), March 22, 2016, through September 30, 2017.

DATES: Applicable September 26, 2018.

FOR FURTHER INFORMATION CONTACT: Jessica Pomper or Peter Zukowski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9122 or (202) 482–0189, respectively.

SUPPLEMENTARY INFORMATION:
Background
The review covers six producers and/or exporters of the subject merchandise. Commerce selected one mandatory respondent, Companhia Siderurgica Nacional (CSN), for individual examination. The producers/exporters that were not selected for individual examination are listed in the “Final Results of the Review” section of this notice.

On July 13, 2018, Commerce published the Preliminary Results. Although we invited parties to comment on the preliminary results of the review, no interested party submitted comments. Accordingly, we are adopting unchanged the Preliminary Results for these final results and no decision memorandum accompanies this Federal Register notice. Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order
The products covered by this order are certain hot-rolled steel flat products from Brazil. For a complete description of the scope of this order, please refer to the Appendix to this notice.

Methodology
In the Preliminary Results, Commerce relied upon facts otherwise available with adverse inferences (AFA) to determine an antidumping margin for CSN because this mandatory respondent did not respond to Commerce’s antidumping duty questionnaire. Because no parties commented on the Preliminary Results, we are adopting in these final results of review the decisions outlined in the Preliminary Results. In accordance with the U.S. Court of Appeals for the Federal Circuit’s decision in Albemarle Corp. v. United States, we are applying to the non-selected respondents the adjusted dumping margin we are applying to CSN in this administrative review. This is the only margin determined in this review for an individual respondent, and thus, it is applicable to the non-selected respondents under section 735(c)(5)(B) of the Act.

Adverse Facts Available
Pursuant to section 776(a) and (b) of the Act, Commerce relied upon AFA to determine an antidumping margin for CSN because this respondent did not respond to Commerce’s antidumping duty questionnaire. For a complete explanation of the analysis underlying the application of AFA, see Preliminary Results.

Final Results of the Review
As a result of this review, we are assigning a dumping margin to the respondents for the period March 22, 2016, through September 30, 2017, as follows:

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1 See Certain Hot-Rolled Steel Flat Products from Brazil: Preliminary Results of the Antidumping Duty Administrative Review; 2016–2017, 83 FR 32632 (July 13, 2018) (Preliminary Results) and accompanying Preliminary Decision Memorandum.
2 See Albemarle Corp. v. United States, 821 F.3d 1345 (Fed. Cir. 2016).
Assessment Rates

Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. Pursuant to section 776(a) and (b) of the Act, Commerce has relied upon facts otherwise available with adverse inferences (AFA) for CSN, and determined a rate adjusted for export subsidies of 30.21. For the companies that were not selected for individual examination, we used as the assessment rate the cash deposit rate assigned to CSN. Commerce intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the reviewed companies will be the rates shown above; (2) for previously investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, or in the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 29.07 percent, the all-others rate established in the LTFV investigation.4 These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as the only reminder to importers of their responsibility, under 19 CFR 351.402(f)(2), to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary’s presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties.

Notification Regarding Administrative Protective Order

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return/ destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this notice of final results of administrative review in accordance with sections 751(a)(1) and 777(i) of the Act and sections 19 CFR 351.213(h) and 351.221(b)(5).


James Maeder,
Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

Scope of the Order

The products covered by this order are certain hot-rolled, flat-rolled steel products, with or without patterns in relief, and whether or not annealed, painted, varnished, or coated with plastics or other non-metallic substances. The products covered do not include those that are clad, plated, or coated with metal. The products covered include coils that have a width or other lateral measurement (“width”) of 12.7 mm or greater, regardless of thickness, and regardless of form of coil (e.g., in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (e.g., in straight lengths) of a thickness of less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, i.e., products which have been “worked after rolling” (e.g., products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

1. where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above unless the resulting measurement makes the product covered by the existing antidumping5 or countervailing duty6 orders on Certain Cut-To-Length Carbon-Quality Steel Plate Products from the Republic of Korea (A–580–836; C–580–837), and
2. where the width and thickness vary for a specific product (e.g., the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, etc.), the measurement at its greatest width or thickness applies.

Steel products included in the scope of this order are products in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and

5 Notice of Amendment of Final Determinations of Sales at Less Than Fair Value and Antidumping Duty Orders: Certain Cut-To-Length Carbon-Quality Steel Plate Products from France, India, Indonesia, Italy, Japan and the Republic of Korea, 65 FR 6585 (February 10, 2000).


4 See Antidumping Duty Order.
(3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.80 percent of molybdenum, or
- 0.10 percent of titanium, or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels, high strength low alloy (HSLA) steels, the substrate for motor lamination steels, Advanced High Strength Steels (AHSS), and Ultra High Strength Steels (UHSS). IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum. The substrate for motor lamination steels contains micro-alloying levels of elements such as silicon and aluminum. AHSS and UHSS are considered high tensile strength and high elongation steels, although AHSS and UHSS are covered whether or not they are high tensile strength or high elongation steels.

Product merchandise includes hot-rolled steel that has been further processed in a third country, including but not limited to pickling, oiling, levelling, annealing, tempering, temper rolling, skin passing, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of the order if performed in the country of manufacture of the hot-rolled steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of this order unless specifically excluded. The following products are outside the scope of this order unless specifically included:

- Ball bearing steels; 8
- Tool steels; 9 and
- Silico-manganese steels.10

The products subject to this order are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.60.0000, 7210.70.3000, 7211.14.0030, 7211.14.0900, 7211.19.1500, 7211.19.2000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000. The HTSUS subheadings above are provided for convenience and U.S. Customs purposes only. The written description of the scope of the order is dispositive.

BILLING CODE 3510–DS–P

SUPPLEMENTARY INFORMATION:

Background

Commerce published the Preliminary Determination in the LTFV investigation of PTFE resin from India on May 7, 2018.1 For a complete description of the events that followed the Preliminary Determination, see the Issues and Decision Memorandum.2

Period of Investigation

The period of investigation is July 1, 2016, through June 30, 2017.

Scope of the Investigation

The product covered by this investigation is PTFE resin from India. For a full description of the scope of this investigation, see the “Scope of the Investigation” in Appendix I of this notice.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs that were submitted by

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8 Ball bearing steels are defined as steels which contain, in addition to iron, each of the following elements by weight in the amount specified: (i) Not less than 0.95 nor more than 1.13 percent of carbon; (ii) not less than 0.22 nor more than 0.48 percent of manganese; (iii) none, or not more than 0.03 percent of sulfur; (iv) none, or not more than 0.03 percent of phosphorus; (v) not less than 0.18 nor more than 0.33 percent of silicon; (vi) not less than 1.25 nor more than 1.65 percent of chromium; (vii) none, or not more than 0.28 percent of nickel; (viii) none, or not more than 0.38 percent of copper; and (ix) none, or not more than 0.09 percent of molybdenum.

9 Tool steels are defined as steels which contain the following combinations of elements in the quantity by weight respectively indicated: (i) More than 1.2 percent carbon and more than 10.5 percent chromium; or (ii) not less than 0.3 percent carbon and 1.25 percent or more but less than 10.5 percent chromium; or (iii) not less than 0.85 percent carbon and 1 percent to 1.8 percent, inclusive, manganese; or (iv) 0.9 percent to 1.2 percent, inclusive, chromium and 0.9 percent to 1.4 percent, inclusive, molybdenum; or (v) not less than 0.5 percent carbon and not less than 3.5 percent molybdenum; or (vi) not less than 0.5 percent carbon and less than 5.5 percent tungsten.

10 Silico-manganese steels are defined as steels containing by weight: (i) Not more than 0.7 percent of carbon; (ii) 0.5 percent or more but not more than 1.9 percent of manganese, and (iii) 0.6 percent or more but not more than 2.3 percent of silicon.

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1 See Polytetrafluoroethylene Resin from India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures, 81 FR 20035 (May 7, 2018) and accompanying Preliminary Decision Memorandum (Preliminary Decision Memorandum) (collectively, Preliminary Determination).

2 See Memorandum, “Issues and Decision Memorandum for the Final Affirmative Determination in the Less Than Fair Value Investigation of Polytetrafluoroethylene Resin from India,” dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).
parties in this investigation are addressed in the Issues and Decision Memorandum. A list of issues raised is attached to this notice at Appendix II. The Issues and Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at http://access.trade.gov and to all parties in Commerce’s Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the internet at http://enforcement.trade.gov/frn/.

Verification
As provided in section 782(l) of the Act, in May and June 2018, we conducted verification of the information reported by the mandatory respondent Gujarat Fluorochemicals Ltd. (GFL) for use in our final determination. We used standard verification procedures, including an examination of relevant accounting and production records and original source documents provided by the respondents.

Changes Since the Preliminary Determination and Use of Adverse Facts Available

Based on our analysis of the comments received and our findings at verification, we made certain changes to the margin calculations for GFL, including the application of facts available with an adverse inference pursuant to section 776(b) of the Act. For a discussion of these changes, see the Issues and Decision Memorandum.

All- Others Rate

Section 735(c)(5)(A) of the Act provides that in the final determination Commerce shall determine an estimated weighted-average dumping margin for all exporters or producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters or producers individually examined, excluding any rates that are zero, de minimis, or determined entirely under section 776 of the Act. In this investigation, we determined a calculated rate for GFL, the one mandatory respondent in this investigation, that is not zero, de minimis, or based entirely on facts otherwise available. Consequently, the rate calculated for this respondent is also assigned as the rate for all other producers and exporters in this investigation.

Final Determination

Commerce determines that the following weighted-average dumping margins exist:

<table>
<thead>
<tr>
<th>Exporter or producer</th>
<th>Estimated weighted-average dumping margin (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gujarat Fluorochemicals Ltd.</td>
<td>22.78</td>
</tr>
<tr>
<td>All-Others</td>
<td>22.78</td>
</tr>
</tbody>
</table>

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days after public announcement of the final determination or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the Federal Register, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of PTFE resin from India as described in Appendix I of this notice, which were entered, or withdrawn from warehouse, for consumption on or after May 7, 2018, the date of publication of the Preliminary Determination of this investigation in the Federal Register. Pursuant to section 735(c)(1)(B) of the Act and 19 CFR 351.210(d), Commerce will instruct CBP to require a cash deposit as follows: (1) The cash deposit rate for the respondent listed above under the Final Determination section will be equal to its estimated weighted-average dumping margin; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the respondent-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; (3) for all other producers or exporters of PTFE resin to the United States, the cash deposit rate will be equal to the all-others rate. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, Commerce will notify the International Trade Commission (ITC) of its final determination. Because the final determination in this proceeding is affirmative, in accordance with section 735(b)(2)(B) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of PTFE resin from India no later than 45 days after Commerce’s final determination. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on appropriate imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Notification Regarding Administrative Protective Order

This notice will serve as a reminder to the parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act and 19 CFR 351.210(c).


Christian Marsh,
Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The product covered by this investigation is polytetrafluoroethylene (PTFE) resin, including but not limited to granular, dispersion, or coagulated dispersion (also known as fine powder). PTFE is covered by the scope of this investigation whether filled or unfilled, whether or not modified, and whether or not containing co-polymer

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3 See the “Discussion of the Issues” section of the Issues and Decision Memorandum; see also Memorandum, “Final Determination Analysis Memorandum for Gujarat Fluorochemicals Ltd.,” (GFL Final Analysis Memorandum) dated concurrently with this notice.

4 See GFL Final Analysis Memorandum.
additives, pigments, or other materials. Also included is PTFE wet raw polymer. The chemical formula for PTFE is C2F4, and the Chemical Abstracts Service Registry number is 9002–84–0. PTFE further processed into micropowder, having particle size typically ranging from 1 to 25 microns, and a melt-flow rate no less than 0.1 gram/10 minutes, is excluded from the scope of this investigation.

PTFE is classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 3904.61.0010 and 3904.61.0090. Subject merchandise may also be classified under HTSUS subheading 3904.69.5000. Although the HTSUS subheadings and CAS Number are provided for convenience and Customs purposes, the written description of the scope is dispositive.

Appendix II
List of Topics Discussed in the Issues and Decision Memorandum
I. Summary
II. Background
III. Scope Comments
IV. Changes Since the Preliminary Determination
V. Use of Adverse Facts Available
VI. Discussion of the Issues
Comment 1: U.S. Sales of Waste and Fines
Comment 2: U.S. Warehousing Expenses
Comment 3: CEP Offset
Comment 4: Sales and Costs Minor Corrections
Comment 5: Cost Adjustments
Comment 6: Low-Pressure Steam
Comment 7: Power
Comment 8: Hydrogen Gas
Comment 9: Chlorine
Comment 10: Calcium Chloride
Comment 11: Exclusion of Packing Costs and Byproduct Revenues from the COGS Denominator
Comment 12: Loss on Sale of Raw Material
Comment 13: Certain Corrections to GPL’s Further Manufacturing Costs Based on Verification Findings
Comment 14: Certain Corrections to Commerce’s Cost Verification Report
VII. Recommendation

Title: Limits of Acceptable Change Study surveys in the Northeast Reserves and Caboleta Island, Puerto Rico.
OMB Control Number: 0648–xxxx.
Form Number(s): None.
Type of Request: Regular (request for a new information collection).
Number of Respondents: 4,273.
Average Hours per Response:
Commercial fishers and water operators, 30 minutes; recreational boaters and visitors, 10 minutes.
Burdens: 777.

Needs and Uses: The Coral Reef Conservation Program (CRCP), developed under the authority of the Coral Reef Conservation Act of 2000, is responsible for programs intended to enhance the conservation of coral reefs. We intend to use the information collected through this instrument for conducting a characterization project utilizing a limits of acceptable change (LAC) framework that encompasses the Puerto Rico Northeast Marine Corridor (NMC) as a continuous management area, addressing the following subjects across the area and within individual natural reserves to create the information base required to promote effective management: Biophysical conditions, social conditions, stakeholder identification, stakeholder uses and use patterns, stakeholder knowledge, attitudes, and beliefs, and stakeholder and resource use conflicts. The study will build on past work conducted with stakeholders on natural resources and social indicators in the region, developing a social conditions baseline. Social conditions will be characterized via a series of stakeholder participation protocols, which will result in stakeholder identification, use and use patterns, knowledge, attitudes, and belief, and use conflicts. It will engage the four, main NMC stakeholders: Commercial fishers; commercial water operators; recreational boaters, and visitors. All commercial fishers and commercial water operators in the region will be surveyed with an in-person questionnaire. Recreational boaters will be reached by sending out an internet/email survey questionnaire sent to all vessel registrants. Visitors in the NMC will be surveyed using an intercept survey administered twice a month at a ferry location and via self-administered surveys disseminated by commercial water operators. It is expected that these multi-pronged approaches will provide the information necessary to complete a stakeholder characterization for the NMC that can be applied to evaluate LAC conditions and trends.

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).


Title: Limits of Acceptable Change Study surveys in the Northeast Reserves and Caboleta Island, Puerto Rico.
OMB Control Number: 0648–xxxx.
Form Number(s): None.
Type of Request: Regular (request for a new information collection).
Number of Respondents: 4,273.
Average Hours per Response:
Commercial fishers and water operators, 30 minutes; recreational boaters and visitors, 10 minutes.
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Affected Public: Business or other for profit organizations; individuals or households.
Frequency: One time.
Respondent’s Obligation: Voluntary.
This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to OIRA Submission@omb.eop.gov or fax to (202) 395–5806.

Sarah Brabson, NOAA PRA Clearance Officer.
[FR Doc. 2018–20851 Filed 9–25–18; 8:45 am]
BILLING CODE 3510–JS–P

DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration

RIN 0648–XG478

Endangered and Threatened Species; Take of Abalone

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.
ACTION: Application for one enhancement permit.

SUMMARY: Notice is hereby given that NMFS has received a permit application request for one new enhancement permit. The proposed work is intended to increase knowledge of species listed under the Endangered Species Act (ESA) and to help guide management, conservation, and recovery efforts. The application may be viewed online at: https://apps.nmfs.noaa.gov/preview/preview_open_for_comment.cfm.

DATES: Comments or requests for a public hearing on the application must be received at the appropriate address or fax number (see ADDRESSES) no later than 5 p.m. Pacific standard time on October 26, 2018.

ADDRESSES: Written comments on the application should be submitted to the Protected Resources Division, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802. Comments may also be submitted via fax to 562–980–4027 or by email to nmfs.swr.applications@noaa.gov (include the permit number in the subject line of the fax or email).

FOR FURTHER INFORMATION CONTACT: Susan Wang, Long Beach, CA (ph.: 562–980–4199, Fax: 562–980–4027, email:...
A marine species, white abalone (Haliotis sorenseni), is discussed in this notice. The NMFS West Coast Region (WCR) has requested a five-year enhancement permit to annually take larval, juvenile, and adult white abalone in California. The permit would be used to experimentally outplant white abalone along the Southern California Coast and determine which methods, locations, habitats, sizes, and densities yield the greatest growth and survival of white abalone. The activities would benefit the listed species by increasing numbers of white abalone in the wild and informing future large-scale outplanting efforts to create self-sustaining populations in locations where white abalone are close to or at local extinction. The NMFS WCR proposes to evaluate three approaches. First, captive-breeding juveniles would be outplanted using two different types of outplanting modules: (1) Baby abalone recruitment trackers (BARTs); and (2) smaller, short-term abalone fixed enclosures (SAFEs). Second, captive-reared larvae would be outplanted using a larval pump module and a net “tent” designed to retain larvae until settlement. Third, captive-breeding adults or wild-collected broodstock would be hand-placed at sites where wild white abalone have been observed. All outplanting would be conducted within the Southern California Bight and would use white abalone maintained and collected under Enhancement Permit 14344–2R, issued under section 10(a)(1)(A) of the ESA to the University of California, Davis—Bodega Marine Laboratory. Growth, survival, genetics, health, and habitat quality would be monitored at regular intervals following outplanting. Post-outplant monitoring would primarily consist of non-lethal, non-capture take to observe, count, measure, and collect samples from abalone. Post-outplant monitoring will occur on a quarterly to annual basis for each outplanting method and will involve collecting shell length, genetic samples, fecal samples, time lapse camera images, and empty shells. The researchers do not intend to kill any listed white abalone, but some may die as an inadvertent result of the research and enhancement activities.

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the applications, associated documents, and comments submitted to determine whether the application meets the requirements of section 10(a) of the ESA and Federal regulations. The final permit decisions will not be made until after the end of the 30-day comment period. NMFS will publish notice of its final action in the Federal Register.

Dated: September 20, 2018
Angela Somma, Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.
DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG478

Atlantic Highly Migratory Species; Atlantic Highly Migratory Species Southeast Data, Assessment, and Review Workshops Advisory Panel

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

ACTION: Notice; nominations for shark stock assessment Advisory Panel.

SUMMARY: NMFS solicits nominations for the “SEDAR Pool,” also known as the Atlantic Highly Migratory Species (HMS) Southeast Data, Assessment, and Review (SEDAR) Workshops Advisory Panel. The SEDAR Pool is comprised of a group of individuals who may be selected to consider data and advise NMFS regarding the scientific information, including but not limited to data and models, used in stock assessments for oceanic sharks in the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea. Nominations are being sought for a 5-year appointment (2019–2024). Individuals with definable interests in the recreational and commercial fishing and related industries, environmental community, academia, and non-governmental organizations will be considered for membership on the SEDAR Pool.

DATES: Nominations must be received on or before October 26, 2018.

ADDRESSES: You may submit nominations and request the SEDAR Pool Statement of Organization, Practices, and Procedures by any of the following methods:
- Email: SEDAR.pool@noaa.gov.
- Mail: Karyl Brewster-Geisz, Highly Migratory Species Management Division, NMFS, 1315 East-West Highway, Silver Spring, MD 20910. Include on the envelope the following identifier: “SEDAR Pool Nomination.”
- Fax: 301–713–1917.

Additional information on SEDAR and the SEDAR guidelines can be found at http://sedarweb.org/. The terms of reference for the SEDAR Pool, along with a list of current members, can be found at https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/southeast-data-assessment-and-review-and-atlantic-highly.

FOR FURTHER INFORMATION CONTACT: Karyl Brewster-Geisz, (301) 425–8503.

SUPPLEMENTARY INFORMATION:

Background

Section 302(g)(2) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 et seq., states that each Council shall establish such advisory panels as are necessary or appropriate to assist it in carrying out its functions under the Act. For the purposes of this section, NMFS applies the above Council provision to Atlantic HMS management (See section 304(g)(1) of the Magnuson-Stevens Act, which provides that the Secretary will prepare fishery management plans for HMS and consult with Advisory Panels under section 302(g) for such FMPs). As such, NMFS has established the SEDAR Pool under this section. The SEDAR Pool currently consists of 26 individuals, each of whom may be selected to review data and advise NMFS regarding the scientific information, including but not limited to data and models, used in stock assessments for oceanic sharks in the Atlantic Ocean, Gulf of Mexico, and Caribbean Sea. While the SEDAR Pool was created specifically for Atlantic oceanic sharks, it may be expanded to include other HMS, as needed.

The primary purpose of the individuals in the SEDAR Pool is to review, at SEDAR workshops, the scientific information (including but not limited to data and models) used in stock assessments that are used to advise NMFS, as a delegate to the Secretary of Commerce (Secretary), about the conservation and management of Atlantic HMS, specifically but not limited to, Atlantic sharks. Individuals in the SEDAR Pool, if selected, may participate in the various data, assessment, and review workshops during the SEDAR process of any HMS stock assessment. In order to ensure that the peer review is unbiased, individuals who participated in a data and/or assessment workshop for a particular stock assessment will not be allowed to serve as reviewers for the same stock assessment. However, these individuals may be asked to attend the review workshop to answer specific questions from the reviewers concerning the data and/or assessment. Members of the SEDAR Pool may serve as members of other Advisory Panels concurrent with, or following, their service on the SEDAR Pool.

Procedures and Guidelines

A. Participants

The SEDAR Pool is comprised of individuals representing the commercial and recreational fishing communities for Atlantic sharks, the environmental community active in the conservation and management of Atlantic sharks, and the academic community that have relevant expertise either with sharks and/or stock assessment methodologies for marine fish species. In addition, individuals who may not necessarily work directly with sharks, but who are involved in fisheries with similar life history, biology and fisheries issues may be part of the SEDAR Pool. Members of the SEDAR Pool must have demonstrated experience in the fisheries, related industries, research, teaching, writing, conservation, or management of marine organisms. The distribution of representation among the interested parties is not defined or limited.

Additional members of the SEDAR Pool may also include representatives from each of the five Atlantic Regional Fishery Management Councils, each of the 18 Atlantic states, both the U.S. Virgin Islands and Puerto Rico, and each of the interstate commissions: The Atlantic States Marine Fisheries Commission and the Gulf States Marine Fisheries Commission.

If NMFS requires additional members to ensure a diverse pool of individuals for data or assessment workshops, NMFS may request individuals to become members of the SEDAR Pool outside of the annual nomination period.

SEDAR Pool members serve at the discretion of the Secretary. Not all members will attend each SEDAR workshop. Rather, NMFS will invite certain members to participate at specific stock assessment workshops dependent on their ability to participate, discuss, and recommend scientific decisions regarding the species being assessed.

NMFS is not obligated to fulfill any requests (e.g., requests for an assessment of a certain species) that may be made by the SEDAR Pool or its individual members. Members of the SEDAR Pool who are invited to attend stock assessment workshops will not be compensated for their services but may be reimbursed for their travel-related expenses to attend such workshops.
B. Nomination Procedures for Appointments to the SEDAR Pool

Member tenure will be for 5 years. Nominations are sought for terms beginning early in 2019 and expiring in 2024. Nomination packages should include:

1. The name, address, phone number, and email of the applicant or nominee;
2. A description of the applicant’s or nominee’s interest in Atlantic shark stock assessments or the Atlantic shark fishery;
3. A statement of the applicant’s or nominee’s background and/or qualifications; and
4. A written commitment that the applicant or nominee shall participate actively and in good faith in the tasks of the SEDAR Pool, as requested.

C. Meeting Schedule

Individual members of the SEDAR Pool meet to participate in stock assessments at the discretion of the Office of Sustainable Fisheries, NMFS. Stock assessment timing, frequency, and relevant species will vary depending on the needs determined by NMFS and SEDAR staff. In 2019, NMFS intends to conduct a benchmark assessment for Atlantic blacktip sharks. In 2020, NMFS intends to begin a research track assessment for the hammerhead shark. During an assessment year, meetings and meeting logistics will be determined according to the SEDAR Guidelines. All meetings are open for observation by the public.


Margo B. Schulze-Haagen,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Survey of Uses of NOAA Ecological Forecasting Products in Western Lake Erie, the Gulf of Mexico, and Chesapeake Bay

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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.

DATES: Written comments must be submitted on or before November 26, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at pracomments@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Lonnie Gonsalves, NOAA National Ocean Service, National Centers for Coastal Ocean Science, 1305 East West Hwy., Rm 8235, Silver Spring, MD 20910 (240) 533–0303, and lonnie.gonsalves@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for a new information collection. In recent years, harmful algal blooms (HABs) and waterborne pathogens such as Vibrio vulnificus have caused major health, ecological, and economic concerns. HABs and other waterborne pathogens can lead to a number of impacts including impaired drinking water, reduced recreational opportunities, and human health impacts from either ingesting affected fish/water or contact with the bloom. To better serve the public and its stakeholders, NOAA has developed forecasts of HABs extent and severity in the western Lake Erie and in the Gulf of Mexico and is finalizing development of a forecast for Vibrio vulnificus in Chesapeake Bay. These forecast products are designed to provide stakeholders and the public with information that can be used to make better decisions that would mitigate the impacts of HABs and waterborne pathogens.

This request is for a set of related surveys to collect information on how stakeholders use NOAA’s ecological forecast products in western Lake Erie, the Gulf of Mexico (the western shore of Florida and the Texas coastline), and Chesapeake Bay. The surveys are designed to collect similar information from the public and other stakeholders across the three geographic regions covered by the forecast products. The information from these surveys will assist NOAA in understanding how stakeholders, including the public, would use the forecast products. This information will help NOAA further improve upon research, development, and delivery of forecast products nationwide.

For western Lake Erie and the Gulf of Mexico, NOAA plans two related surveys in each region. First, NOAA will collect information from the public on how using the information in the forecast products would affect decisions related to fishing, swimming and boating. A companion survey would ask charter boat operators on Lake Erie how information in the forecast would affect their decisions regarding fishing operations. These activities (fishing, swimming and boating) reflect the types of activities likely to be affected by HABs in each area. Drinking water is also at risk in Lake Erie due to HABs, but NOAA has information on how drinking water facilities respond to HABs and is also discussing use of the forecast products with a small (fewer than 10) number of drinking water facilities.

For Chesapeake Bay, NOAA would implement one survey focused on recreational swimmers. The primary risk posed by Vibrio vulnificus is through contact with the bacterium; thus, NOAA determined that focusing on recreational swimmers use of the forecast product would be the most productive approach.

II. Method of Collection

NOAA plans to collect these data using an online data collection firm to select public samples and administer the survey via the internet. For the charter boat surveys, NOAA will work with charter boat associations in the Lake Erie and Gulf of Mexico areas to distribute the survey link to their memberships. Data collection will focus on a small sample of drinking water and natural resource managers, public health officials, charter boat operators, and the public. NOAA is not concerned with collecting statistically representative data at this time as the limited sampling will adequately address how the public may use the data from the aforementioned HAB and pathogen forecasts.

III. Data

OMB Control Number: 0648–xxxx.

Form Number(s): None.

Type of Review: Regular submission (new information collection).

Affected Public: Individuals or households; business or other for-profit organizations.

Estimated Number of Respondents: 600.

Estimated Time per Response: 15 minutes.
IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.


Sarah Brabson,
NOAA PRA Clearance Officer.

[FR Doc. 2018–20850 Filed 9–25–18; 8:45 am]

DEPARTMENT OF COMMERCE
National Telecommunications and Information Administration

[Docket No. 180821780–8780–01]
RIN 0660–XC043

Developing the Administration’s Approach to Consumer Privacy

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice; request for public comments.

SUMMARY: On behalf of the U.S. Department of Commerce, the National Telecommunications and Information Administration (NTIA) is requesting comments on ways to advance consumer privacy while protecting prosperity and innovation. NTIA is seeking public comments on a proposed approach to this task that lays out a set of user-centric privacy outcomes that underpin the protections that should be produced by any Federal actions on consumer-privacy policy, and a set of high-level goals that describe the outlines of the ecosystem that should be created to provide those protections.

DATES: Comments must be received by 11:59 p.m. Eastern Daylight Time on October 26, 2018.

ADDRESSES: Written comments identified by Docket No. 180821780–8780–01 may be submitted by email to privacyrfc2018@ntia.doc.gov. Comments submitted by email should be machine-readable and should not be copyprotected. Written comments also may be submitted by mail to the National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 4725, Attn: Privacy RFC, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT:

For media inquiries: Anne Veigele, Director, Office of Public Affairs, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 4897, Washington, DC 20230; telephone: (202) 482–7002; email: press@ntia.doc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The U.S. Department of Commerce (Department) requests comment on ways to advance consumer privacy while protecting prosperity and innovation. Every day, individuals interact with an array of products and services, many of which have become integral to their daily lives. Often, especially in the digital environment, these products and services depend on the collection, retention, and use of personal data about their users. Users must therefore trust that organizations will respect their interests, understand what is happening with their personal data, and decide whether they are comfortable with this exchange. Trust is at the core of the United States’ privacy policy formation. Through this Request for Comment (RFC), the Administration will determine the best path toward protecting individual’s privacy while fostering innovation.

The time is ripe for this Administration to provide the leadership needed to ensure that the United States remain at the forefront of enabling innovation with strong privacy protections. A growing number of foreign countries, and some U.S. states, have articulated distinct visions for how to address privacy concerns, leading to a nationally and globally fragmented regulatory landscape. Such fragmentation naturally disincentivizes innovation by increasing the regulatory costs for products that require scale. The Administration hopes to articulate a renewed vision, one that reduces fragmentation nationally and increases harmonization and interoperability nationally and globally.

Further, changes in the way personal information is used by organizations, and how users interact with the products and services with which they frequently engage, have increased the belief that users are losing control over their personal information. As seen in data collected by the National Telecommunications and Information Administration (NTIA), at least a third of online households have been deterred from certain forms of online activity, such as financial transactions, due to privacy and security concerns. The Administration takes these concerns seriously and believes that users should be able to benefit from dynamic uses of their information, while still expecting organizations will appropriately minimize risks to users’ privacy. Risk-based flexibility is therefore at the heart of the approach the Administration is requesting comment on in this RFC. We are mindful of the potential impact of a solution on small and mid-sized businesses, and we will be looking for solutions that support their continued ability to innovate and support economic growth.

The United States has a history of providing strong protections for privacy dating back to 1789, with the drafting of our Bill of Rights, including the Fourth Amendment. The United States also has been a leader in developing privacy norms, be it through the development of Fair Information Practice Principles (FIPPs) in the 1970’s, or through the strongest privacy enforcement regime in the world. For users of products and services in several sectors (e.g., healthcare, education, financial services), specific laws cover how organizations handle personal information. Where no sector-specific laws apply, the Federal Trade Commission (FTC) has the authority to ensure that organizations are not deceiving consumers or operating unfairly. In all respects, the United States...
States has successfully investigated and taken enforcement actions against organizations that violate these existing Federal laws. This RFC asks how best to strengthen the protections users currently enjoy; it does not propose changing current sectoral federal laws.\(^2\)

This RFC is the outcome of an interagency process led by the National Economic Council (NEC) of the United States. NTIA has worked in coordination with the International Trade Administration (ITA) to ensure consistency with international policy objectives, and in parallel with the work of the National Institute of Standards and Technology (NIST) in developing a voluntary risk-based Privacy Framework as an enterprise risk management tool for organizations. In developing this RFC, the Department conducted significant outreach to a diverse set of individuals and organizations, including a broad range of industries, academics, and civil society organizations. These meetings helped to shape this Administration’s proposed general approach to privacy, described below.

This approach is divided into two parts: (1) A set of user-centric privacy outcomes that underpin the protections that should be produced by any Federal actions on consumer-privacy policy, and (2) a set of high-level goals that describe the outlines of the ecosystem that should be created to provide those protections. This Administration is approaching this subject with humility, an understanding of the complexity of the issues at hand, and a commitment to a transparent process. As such, this RFC does not call for the creation of a statutory standard. Rather, it is looking to commenters to respond with details as to how these privacy outcomes and goals can be achieved. These comments will help to inform future Administration policy, actions, and engagement on consumer privacy.\(^3\)

A. Privacy Outcomes

Principle-based approaches to privacy, particularly when written to be operationalized, often encapsulate the desired outcome and the means used to achieve this outcome. For example, the consent of an informed user is the endgoal of most approaches to consumer privacy, but in order to create legal clarity, this principle is implemented by mandating notice and choice. To date, such mandates have resulted primarily in long, legal, regulator-focused privacy policies and check boxes, which only help a very small number of users who choose to read these policies and make binary choices.

The Administration is instead proposing that discussion of consumer privacy in the United States refocus on the outcomes of organizational practices, rather than on dictating what those practices should be. The desired outcome is a reasonably informed user, empowered to meaningfully express privacy preferences, as well as products and services that are inherently designed with appropriate privacy protections, particularly in business contexts in which relying on user intervention may be insufficient to manage privacy risks. Using a risk-based approach, the collection, use, storage, and sharing of personal data should be reasonable and appropriate to the context. Similarly, user transparency, control, and access should be reasonable and appropriate relative to context. This outcome underpins many of the principle-based approaches, including the FIPPs. The Administration is proposing that these outcomes be operationalized through a risk-management approach, one that affords organizations flexibility and innovation in how to achieve these outcomes.

Protecting both privacy and innovation requires balancing flexibility with the need for legal clarity and strong consumer protections. Being overly prescriptive can result in compliance checklists that stymie innovative privacy solutions. In addition, a prescriptive approach does not necessarily provide measurable privacy benefits. An outcome-based approach emphasizes flexibility, consumer protection, and legal clarity can be achieved through mechanisms that focus on managing risk and minimizing harm to individuals arising from the collection, storage, use, and sharing of their information.

The following outcomes are provided to spur comments, discussion, and engagement on how best to achieve user-centric privacy outcomes in a manner that is both flexible and clear, not to propose the text of a legal standard. They should be read as a set of inputs for building better privacy protections into products and services. For example, Access and Correction (item 5, below) is not an abstract requirement. Rather, organizations should consider the overall context in which the product or service operates, including the purpose of the product or service, the privacy risks that the product or service may be creating, other means of mitigating these privacy risks, the impact of access and correction on other organizational risks, and other relevant factors, in order to determine the degree or manner in which access and correction could help achieve a user-centric privacy outcome without creating needless costs.

1. Transparency. Users should be able to easily understand how an organization collects, stores, uses, and shares their personal information. Transparency can be enabled through various means. Organizations should take into account how the average user interacts with a product or service, and maximize the intuitiveness of how it conveys information to users. In many cases, lengthy notices describing a company’s privacy program at a consumer’s initial point of interaction with a product or service does not lead to adequate understanding. Organizations should use approaches that move beyond this paradigm when appropriate.

2. Control. Users should be able to exercise reasonable control over the collection, use, storage, and disclosure of the personal information they provide to organizations. However, which controls to offer, when to offer them, and how they are offered should depend on context, taking into consideration factors such as a user’s expectations and the sensitivity of the information. The controls available to users should be developed with intuitiveness of use, affordability, and accessibility in mind, and should be made available in ways that allow users to exercise informed decision-making. In addition, controls used to withdraw the consent of, or to limit activity previously permitted by, a consumer should be as readily accessible and usable as the controls used to permit the activity.

3. Reasonable Minimization. Data collection, storage length, use, and sharing by organizations should be minimized in a manner and to an extent that is reasonable and appropriate to the context and risk of privacy harm. Other means of reducing the risk of privacy harm (e.g., additional security safeguards or privacy enhancing techniques) can help to reduce the need for such minimization.

4. Security. Organizations that collect, store, use, or share personal information should employ security safeguards to secure these data. Users should be able to expect that their data are protected from loss and unauthorized access, destruction, use, modification, and disclosure. Further, organizations should take reasonable security.
measures appropriate to the level of risk associated with the improper loss of, or improper access to, the collected personal data; they should meet or ideally exceed current consensus best practices, where available. Organizations should secure personal data at all stages, including collection, computation, storage, and transfer of raw and processed data.

5. Access and Correction. Users should have qualified access personal data that they have provided, and to rectify, complete, amend, or delete this data. This access and ability to correct should be reasonable, given the context of the data flow, appropriate to the risk of privacy harm, and should not interfere with an organization’s legal obligations, or the ability of consumers and third parties to exercise other rights provided by the Constitution, and U.S. law, and regulation.

6. Risk Management. Users should expect organizations to take steps to manage and/or mitigate the risk of harmful uses or exposure of personal data. Risk management is the core of this Administration’s approach, as it provides the flexibility to encourage innovation in business models and privacy tools, while focusing on potential consumer harm and maximizing privacy outcomes.

7. Accountability. Organizations should be accountable externally and within their own processes for the use of personal information collected, maintained, and used in their systems. As described below in the High-Level Goals for Federal Action section, external accountability should be structured to incentivize risk and outcome-based approaches within organizations that enable flexibility, encourage privacy-by-design, and focus on privacy outcomes. Organizations that control personal data should also take steps to ensure that their third-party vendors and services are accountable for their use, storage, processing, and sharing of that data.

B. High-Level Goals for Federal Action

The Administration is also looking to gather feedback on the following high-level goals for Federal action. These goals should be understood as setting the broad outline for the direction that Federal action should take, in addition to comments on the goals, we are also looking for comments with details as to how these goals can be achieved. Below is a non-exhaustive and non-prioritized list of the Administration’s priorities. We understand that there is considerable work to be done to achieve these goals.

1. Harmonize the regulatory landscape. While the sectoral system provides strong, focused protections and should be maintained, there is a need to avoid duplicative and contradictory privacy-related obligations placed on organizations. We are actively witnessing the production of a patchwork of competing and contradictory baseline laws. This emerging patchwork harms the American economy and fails to improve privacy outcomes for individuals, who may be unaware of what their privacy protections are, and who may not have equal protections, depending on where the user lives. Steps need to be taken to ensure that the regulatory landscape for organizations that process personal data in the United States remains flexible, strong, predictable, and harmonized.

2. Legal clarity while maintaining the flexibility to innovate. The ideal end-state would ensure that organizations have clear rules that provide for legal clarity, while enabling flexibility that allows for novel business models and technologies. This means to use a variety of methods to achieve consumer-privacy outcomes. The Administration understands that balancing legal clarity, flexibility, and consumer privacy requires compromise and creative thinking. It is in striking this balance, however, that the United States has been able to maintain international leadership in both innovation and privacy enforcement, and any future action should strive to create a system that to the greatest extent possible maximizes each.

3. Comprehensive application. Any action addressing consumer privacy should apply to all private sector organizations that collect, store, use, or share personal data in activities that are not covered by sectoral laws. The differences between business models and technologies used should be addressed through the application of a risk and outcome-based approach, which would allow for similar data practices in similar context to be treated the same rather than through a fragmented regulatory approach.

4. Employ a risk and outcome-based approach. Instead of creating a compliance model that creates cumbersome red tape—without necessarily achieving measurable privacy protections—the approach to privacy regulations should be based on risk modeling and focused on creating user-centric outcomes. Risk-based approaches allow organizations the flexibility to balance business needs, consumer expectations, legal obligations, and potential privacy harms, among other inputs, when making decisions about how to adopt various privacy practices. Outcome-based approaches also enable innovation in the methods used to achieve privacy goals. Risk and outcome-based approaches have been successfully used in cybersecurity, and can be enforced in a way that balances the needs of organizations to be agile in developing new products, services, and business models with the need to provide privacy protections to their customers, while also ensuring clarity in legal compliance.

5. Interoperability. The growth and advancement of the internet-enabled economy depends on personal information moving seamlessly across borders. However, the Administration recognizes that governments approach consumer privacy differently, creating the need for mechanisms to bridge differences, while ensuring personal data remains protected. The Administration should therefore seek to reduce the friction placed on data flows by developing a regulatory landscape that is consistent with the international norms and frameworks in which the United States participates, such as the APEC Cross-Border Privacy Rules System.

6. Incentivize privacy research. The U.S. Government should encourage more research into, and development of, products and services that improve privacy protections. These technologies and solutions will include measures built into system architectures or product design to mitigate privacy risks, as well as usability features at the user-interface level. These innovations require more research into understanding user preferences, concerns, and difficulties, as well as an understanding of the impact on legal obligations of third parties and the ability of third parties to exercise other rights provided by law. Privacy research will inform the development of standards frameworks, models, methodologies, tools, and products that enhance privacy.

7. FTC enforcement: Given its history of effectiveness, the FTC is the appropriate federal agency to enforce consumer privacy with certain exceptions made for sectoral laws outside the FTC’s jurisdiction, such as HIPAA. It is important to take steps to ensure that the FTC has the necessary resources, clear statutory authority, and direction to enforce consumer privacy laws in a manner that balances the need for strong consumer protections, legal clarity for organizations, and the flexibility to innovate.

8. Scalability: The Administration should ensure that the proverbial sticks
used to incentivize strong consumer privacy outcomes are deployed in proportion to the scale and scope of the information an organization is handling. In general, small businesses that collect little personal information and do not maintain sensitive information about their customers should not be the primary targets of privacy-enforcement activity, so long as they make good-faith efforts to utilize privacy protections. Similarly, there should be a distinction between organizations that control personal data and third-party vendors that merely process that personal data on behalf of other organizations. Just as organizations should employ outcome-based approaches when developing privacy protections for their customers, the government should do the same with its approach to privacy enforcement and compliance.

II. Request for Comment

A. Through this RFC, the Department is first seeking feedback on what it believes are the core privacy outcomes that consumers can expect from organizations.

1. Are there other outcomes that should be included, or outcomes that should be expanded upon as separate items?
2. Are the descriptions clear? Beyond clarity, are there any issues raised by how any of the outcomes are described?
3. Are there any risks that accompany the list of outcomes, or the general approach taken in the list of outcomes?

B. The Department is also seeking feedback on the proposed high-level goals for U.S. consumer-privacy protections.

1. Are there other goals that should be included, or outcomes that should be expanded upon?
2. Are the descriptions clear? Beyond clarity, are there any issues raised by how the issues are described?
3. Are there any risks that accompany the list of goals, or the general approach taken by the Department?

C. The Department is seeking comments that describe what the next steps and measures the Administration should take to effectuate the previously discussed user-centric privacy outcomes, and to achieve an end-state in line with the high-level goals. In particular:

1. Are there any aspects of this approach that could be implemented or enhanced through Executive action, for example, through procurement? Are there any non-regulatory actions that could be undertaken? If so, what actions should the Executive branch take?
2. Should the Department convene people and organizations to further explore additional commercial data privacy-related issues? If so, what is the recommended focus and desired outcomes?
3. What aspects of the Department’s proposed approach to consumer privacy, if any, are best achieved via other means? Are there any recommended statutory changes?
4. The Department understands that some of the most important work in establishing privacy protections lies within the definitions of key terms, and seeks comments on the definitions. In particular:

   1. Do any terms used in this document require more precise definitions?
   2. Are there suggestions on how to better define these terms?
   3. Are there other terms that would benefit from more precise definitions?
   4. What should those definitions be?

E. One of the high-level end-state goals is for the FTC to continue as the Federal consumer privacy enforcement agency, outside of sectoral exceptions beyond the FTC’s jurisdiction. In order to achieve the goals laid out in this RFC, would changes need to be made with regard to the FTC’s resources, processes, and/or statutory authority?

F. If all or some of the outcomes or high-level goals described in this RFC were replicated by other countries, do you believe it would be easier for U.S. companies to provide goods and services in those countries?

G. Are there other ways to achieve U.S. leadership that are not included in this RFC, or any outcomes or high-level goals in this document that would be detrimental to achieving the goal of achieving U.S. leadership?

Instructions for Commenters

This is a general solicitation of comments from the public. We invite comments on the full range of questions presented by this RFC and on issues that are not specifically raised. Commenters are encouraged to address any or all of the questions above. Comments that contain references to specific court cases, studies, and/or research should include copies of the referenced materials along with the submitted comments. Commenters should include the name of the person or organization filing the comment, as well as a page number on each page of the submissions. All comments received are a part of the public record and will generally be posted on the NTIA website, www.ntia.doc.gov/privacyrfc2018, without change. All personal identifying information (for example, name or address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.


David J. Redl,
Assistant Secretary for Communications and Information, National Telecommunications and Information Administration.

[FR Doc. 2018–20941 Filed 9–25–18; 8:45 am]
BILLING CODE 3510–60–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities Under OMB Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

DATES: Comments must be submitted on or before October 26, 2018.

ADDRESSES: Comments regarding the burden estimate or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs (OIRA) in OMB within 30 days of this notice’s publication by either of the following methods. Please identify the comments by “OMB Control No. 3038–0069.”

• By email addressed to:
  OIRAsubmissions@omb.eop.gov or
• By mail addressed to: the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW, Washington DC 20503.

A copy of all comments submitted to OIRA should be sent to the Commodity Futures Trading Commission (the “Commission”) by either of the following methods. The copies should refer to “OMB Control No. 3038–0069.”

• By email addressed to: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581;
• By Hand Delivery/Courier to the same address; or
• Through the Commission’s website at http://comments.cftc.gov. Please follow the instructions for submitting comments through the website. A copy of the supporting statement for the collection of information discussed herein may be obtained by visiting http://RegInfo.gov.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to http://www.cftc.gov. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in §145.9 of the Commission’s regulations. The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from http://www.cftc.gov that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT:
Eileen Chotiner, Senior Compliance Analyst, Division of Clearing and Risk, Commodity Futures Trading Commission, (202) 418–5467; email: echotiner@cftc.gov, and refer to OMB Control No. 3038–0069.

SUPPLEMENTARY INFORMATION:
Title: “Information Management Requirements for Derivatives Clearing Organizations,” (OMB Control No. 3038–0069). This is a request for extension and revision of a currently approved information collection.

Abstract: Part 39 of the Commission’s regulations establishes information management requirements for registered DCOs. The Commission will use the information in this collection to assess compliance of DCOs with requirements for DCOs prescribed in the Commodity Exchange Act and Commission regulations. 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. On July 24, 2018, the Commission published in the Federal Register notice of the proposed extension of this information collection and provided 60 days for public comment on the proposed extension, 83 FR 34986 (“60-Day Notice”). The Commission received no relevant comments on the 60-Day Notice.

Burden Statement: The Commission is revising its estimate of the burden for this collection for 16 registered DCOs. The respondent burden for this collection is estimated to be as follows:


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<th>Estimated number of respondents per year</th>
<th>Reports annually by each</th>
<th>Total annual responses</th>
<th>Estimated average number of hours per response</th>
<th>Estimated total annual burden hours</th>
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3. Event-specific reporting Requirements for Derivatives Clearing Organizations (Regulation 39.19).

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</table>

17 CFR 145.9.
2 16 respondents × 250 annual responses per respondent = 4000 total responses, × 0.1 hours per response = 400 total annual burden hours.
3 16 respondents × 1 annual response per respondent = 16 total responses, × 2606 hours per response = 41,696 total annual burden hours.
4 16 respondents × 4 annual responses per respondent = 64 total responses, × 5.6 hours per response = 358.4 total annual burden hours.
Respondents/Affected Entities: Derivatives clearing organizations (DCOs).  
Estimated annual number of respondents: 16.5  
Estimated average burden hours per respondent: 10.6  
Annual responses by each respondent: 256.  
Estimated total annual burden hours: 44,054.  
Frequency of Collection: Daily, annually and on occasion.  
There are no capital costs or operating and maintenance costs associated with this collection.  
(Authority: 44 U.S.C. 3501 et seq.)  
Robert Sidman,  
Deputy Secretary of the Commission.  
[FR Doc. 2018–20949 Filed 9–25–18; 8:45 am]  
BILLING CODE 6351–01–P  

COMMODITY FUTURES TRADING COMMISSION  

AGENCY INFORMATION COLLECTION ACTIVITIES UNDER OMB REVIEW  

AGENCY: Commodity Futures Trading Commission.  

ACTION: Notice.  

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (PRA), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.  

DATES: Comments must be submitted on or before October 26, 2018.  

ADDRESSES: Comments regarding the burden estimate or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs (OIRA) in OMB within 30 days of this notice’s publication by either of the following methods. Please identify the comments by “OMB Control No. 3038–0076.”  

• By email addressed to: OIRASubmissions@omb.eop.gov or  
• By mail addressed to: The Office of Information and Regulatory Affairs, Office of Management and Budget, Attention Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW, Washington DC 20503.  

A copy of all comments submitted to OIRA should be sent to the Commodity Futures Trading Commission (the “Commission”) by either of the following methods. The copies should refer to “OMB Control No. 3038–0076.”  

• By mail addressed to: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581;  
• By Hand Delivery/Courier to the same address; or  
• Through the Commission’s website at https://comments.cftc.gov. Please follow the instructions for submitting comments through the website.  

A copy of the supporting statement for the collection of information discussed herein may be obtained by visiting https://RegInfo.gov.  

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to https://www.cftc.gov. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission’s regulations.1 The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from https://www.cftc.gov that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.  

FOR FURTHER INFORMATION CONTACT: Eileen Chotiner, Senior Compliance Analyst, Division of Clearing and Risk, Commodity Futures Trading Commission, (202) 418–5467; email: echotiner@cftc.gov.  

SUPPLEMENTARY INFORMATION:  

Title: Part 39, Risk Management Requirements for Derivatives Clearing Organizations, (OMB Control No. 3038–0076). This is a request for extension and revision of a currently approved information collection.  

Abstract: Commission Regulations 39.12, 39.13, 39.14, 39.15, 39.16 and 39.18 establish risk management requirements for registered derivatives clearing organizations (“DCOs”). Regulation 39.3 requires any person seeking to register as a DCO to submit a completed Form DCO as provided in the appendix to part 39, accompanied by all applicable exhibits. The Commission will use the information in this collection to assess compliance of DCOs and DCO applicants with requirements for DCOs prescribed in the Commodity Exchange Act and Commission regulations.  

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. On July 13, 2018, the Commission published in the Federal Register notice of the proposed extension of this information collection and provided 60 days for public comment on the proposed extension. 83 FR 32638 (“60-Day Notice”). The Commission did not receive any relevant comments on the 60-Day Notice.  

Burden Statement: For this collection, the Commission is revising its burden estimate for 16 registered DCOs and 3 potential DCO applicants, as follows: 


5 Includes 16 currently registered DCOs (an increase of 2 since the last extension).  
6 Since burden hours vary widely within the collection (see above tables), this is the average of burden hours per response for the collection as a whole (aggregate of 2661.7 hours per response/aggregate of 260 responses = 10.24 hours, rounded to 10).  

17 CFR 145.9.
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<tr>
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<td>2. Collection 3038–0076—Event-Specific System Safeguards Reporting Requirements for Derivatives Clearing Organizations (Regulations 39.18(g) and (h)).</td>
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<td>50</td>
<td>800</td>
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</table>

Types of Respondents/Affected Entities: Derivatives clearing organizations (DCOs) and applicants for registration as a DCO.

Estimated annual number of respondents: 19.2

Estimated average burden hours per response: 9.3

Estimated total annual burden hours: 2003.4

Frequency of Collection: On occasion.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 et seq.)

Dated: September, 21, 2018.

Robert Sidman,
Deputy Secretary of the Commission.

[FR Doc. 2018–20948 Filed 9–25–18; 8:45 am]
BILLING CODE 6351–01–P

CONSUMER PRODUCT SAFETY COMMISSION
Sunshine Act Meetings
TIME AND DATE: Wednesday, October 3, 2018, 10:00 a.m.–12:00 p.m.
PLACE: Hearing Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, MD.
STATUS: Commission Meeting—Open to the Public.
MATTER TO BE CONSIDERED: Briefing Matter: Final Rule to Revise Current Fireworks Regulation.

A live webcast of the Meeting can be viewed at https://www.cpsc.gov/live.


Dated: September 24, 2018.
Alberta E. Mills,
Secretary.

[FR Doc. 2018–21109 Filed 9–24–18; 4:15 pm]
BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE
Department of the Air Force
Notice of Availability of Software and Documentation for Licensing

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Availability of VIGILANT SPIRIT Software and Documentation for Licensing.

SUMMARY: The Department of the Air Force announces the availability of VIGILANT SPIRIT software and related documentation that enables flexible operator teaming arrangements, including single operator control, of multiple heterogeneous Unmanned Air Vehicles (“UAVs”).

ADDRESSES: Licensing interests should be sent to: Office of Research and Technology Applications, 711 HPW/XPO, 2610 Seventh Street, Wright Patterson AFB, OH 45433; Facsimile: (937) 656–7959;
or Dr. James D. Kearns, (937) 255–3765.

FOR FURTHER INFORMATION CONTACT: Office of Research and Technology Applications, 711 HPW/XPO, 2610 Seventh Street, Wright Patterson AFB, OH 45433; Facsimile: (937) 656–7959; or Dr. James D. Kearns, (937) 255–3765.

SUPPLEMENTARY INFORMATION: The VIGILANT SPIRIT (“VS”) software suite includes the VS Control Station
DEPARTMENT OF DEFENSE
Office of the Secretary
Membership of the Performance Review Board

AGENCY: Office of the Secretary of Defense (OSD), DoD.

ACTION: Notice of board membership.


DATES: The board membership is applicable beginning on September 11, 2018.

FOR FURTHER INFORMATION CONTACT: Laura E. Devlin Dominguez, Assistant Director for Office of the Secretary of Defense Senior Executive Management Office, Office of the Deputy Chief Management Officer, Department of Defense, (703) 693–8373.

SUPPLEMENTARY INFORMATION: The publication of PRB membership is required by 5 U.S.C. 4314(c)(4). In accordance with 5 U.S.C. 4314(c)(4), the following executives are appointed to the Office of the Secretary of Defense PRB with specific PRB panel assignments being made from this group. Executives listed will serve a one-year renewable term, beginning September 11, 2018.

Office of the Secretary of Defense

Appointing Authority—Patrick M. Shanahan, Deputy Secretary of Defense
Principal Executive Representative—Michael L. Rhodes
Chairperson—Glenda H. Scheiner

PRB PANEL MEMBERS

ABERCROMBIE, CARA L.
AHMED, SAJEEEL S.
ATKINSON, MICHELLE CRESSWELL
BAKER, JAMES H.
BARNA, STEPHANIE A.
BECK, REBECCA S.
BEEBE, MATTHEW R.
BENJAMIN, MICHAEL A.
BELOUGHER, GUY C.
BLANKS, JULIA L.
BOOTH, SR., WILLIAM H.
BRUHN, MICHAEL L.
CADMAN, DAVID S.
CARNEY, JR., THOMAS F.
CONDON, CHRISTINE M.
EARY, WALTER B.
FOGG, GLENN A.
FRENCH, KRISTIN K.
GARRETT, RONNA L.
GILLISON, AARON P.
GRAFF, DIANA P.
HENRY, THOMAS M.
HIGGINS, MAUREEN B.
HILL, JOHN D.
IRWIN, JR., THOMAS C.
KOFFSKY, PAUL S.
LAYCHAK, MICHAEL R.
MARTIN, JASON G.
MAYS, WILLIAM D.
MEYERS, KAREN F.
MICHELLI, THOMAS P.
MUCHMORE, LORA H.
MUSGRAVE, DAVID L.
ODONNELL, CHRIS.
POTOCHEY, PETER J.
REARDON, DELINE R.
REED, JEFFREY R.
SCHLOSS, SCOTT R.
SHELDERS, JR., MICHAEL E.
VAN WINKLE, ELIZABETH P.
WALSH, JENNIFER C.
WEATHERINGTON, DYKE D.


Aaron T. Siegel,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY
Notice of Orders Issued Under Section 3 of the Natural Gas Act During August 2018

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during August 2018, it issued orders granting authority to import and export natural gas, to import and export liquefied natural gas (LNG), to Amend Long-Term-Multi-Contract Authorization to Export LNG, and to Allow Electronic Service in Proceeding. These orders are summarized in the attached appendix and may be found on the FE website at https://www.energy.gov/fe/listing-doefe-authorizationsorders-issued-2018-0.

They are also available for inspection and copying in the U.S. Department of Energy (FE–34), Division of Natural Gas Regulation, Office of Regulation, Analysis, and Engagement, Office of Fossil Energy, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on September 21, 2018.

Amy Sweeney,
Director, Division of Natural Gas Regulation.

Appendix
Deputy Secretary.


Nathaniel J. Davis, Sr.,
Deputy Secretary.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER18–2448–000]

Robindale Retail Power Services, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Robindale Retail Power Services, LLC’s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

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 October 9, 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 appropriate link in the above list. They are also available for electronic review in the Commission’s Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERConlineSupport@ferc.gov or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

[FR Doc. 2018–20915 Filed 9–25–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–1618–001.

Applicants: Arizona Public Service Company.

Description: Compliance filing; Primary Frequency Response
Compliance Filing to be effective 5/15/2018.

Filed Date: 9/19/18.
Accession Number: 20180919–5066.
Comments Due: 5 p.m. ET 10/10/18.
Applicants: Southwest Power Pool, Inc.

Description: Compliance filing:
3388R1 East River/Otter Tail/MISO Int Agr Compliance Filing to be effective 9/17/2018.

Filed Date: 9/19/18.
Accession Number: 20180919–5008.
Comments Due: 5 p.m. ET 10/10/18.
Applicants: Midcontinent Independent System Operator, Inc.

Description: Tariff Amendment: 2018–09–19 SA 3134 ETI-Liberty County Solar Project GIA (J483) 2nd Amendment to be effective 7/13/2018.

Filed Date: 9/19/18.
Accession Number: 20180919–5125.
Comments Due: 5 p.m. ET 10/10/18.
Docket Numbers: ER18–2074–000.
Applicants: AEP Texas Inc.

Description: Report Filing: AEPTX-Pedernales EC TSA—Amend & Restated—Supplement to be effective N/A.

Filed Date: 9/18/18.
Accession Number: 20180918–5054.
Comments Due: 5 p.m. ET 10/9/18.
Docket Numbers: ER18–2449–000.

Description: § 205(d) Rate Filing: 2018–09–19 SA 3167 Enbridge-SWL&P Facilities Reimbursement Agrnt (Nemadji) to be effective 9/19/2018.

Filed Date: 9/18/18.
Accession Number: 20180918–5080.
Comments Due: 5 p.m. ET 10/9/18.
Docket Numbers: ER18–2450–000.
Applicants: Basin Electric Power Cooperative, Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Basin Electric Power Cooperative Formula Rate Revisions to be effective 1/1/2017.

Filed Date: 9/18/18.
Accession Number: 20180918–5092.
Comments Due: 5 p.m. ET 10/9/18.
Docket Numbers: ER18–2451–000.
Applicants: Lockhart Power Company.

Description: Application for Reclassification as a Category 1 Seller of Lockhart Power Company.

Filed Date: 9/18/18.
Accession Number: 20180918–5114.
Comments Due: 5 p.m. ET 10/9/18.
Docket Numbers: ER18–2452–000.
Applicants: National Choice Energy LLC.

Description: Notice of Cancellation of MBR tariff of National Choice Energy LLC.

Filed Date: 9/18/18.
Accession Number: 20180918–5124.
Comments Due: 5 p.m. ET 10/9/18.
Docket Numbers: ER18–2453–000.
Applicants: Mid-Atlantic Interstate Transmission, LLC, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing:
NEXUS Negotiated Rate Agreements
§ 4(d) Rate Filing: 091918
NEXUS Negotiated Rate Agreements
First Year of Service—Compliance Filing.

Filed Date: 9/19/18.
Accession Number: 20180919–5031.
Comments Due: 5 p.m. ET 10/1/2018.
Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 091918

Filed Date: 9/19/18.
Accession Number: 20180919–5016.
Comments Due: 5 p.m. ET 10/1/2018.
Docket Numbers: RP18–1189–000.
Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 091918

Filed Date: 9/19/18.
Accession Number: 20180919–5017.
Comments Due: 5 p.m. ET 10/1/2018.
Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 091918

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

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: Transcontinental Gas Pipe Line Company, LLC submits an application to amend the Commission’s certificate authorizing the Gulf Connector Expansion Project under CP16–494.

Filed Date: 9/7/18.
Accession Number: 20180907–5124.
Comments Due: 5 p.m. ET 9/28/18.
Applicants: Equitrans, L.P.

Description: Compliance filing EFT First Year of Service—Compliance Filing.

Filed Date: 9/19/18.
Accession Number: 20180919–5031.
Comments Due: 5 p.m. ET 10/1/2018.
Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 091918

Filed Date: 9/19/18.
Accession Number: 20180919–5016.
Comments Due: 5 p.m. ET 10/1/2018.
Docket Numbers: RP18–1189–000.
Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 091918

Filed Date: 9/19/18.
Accession Number: 20180919–5017.
Comments Due: 5 p.m. ET 10/1/2018.
Applicants: Iroquois Gas Transmission System, L.P.

Description: § 4(d) Rate Filing: 091918

Filed Date: 9/19/18.
Accession Number: 20180919–5018.
Comments Due: 5 p.m. ET 10/2/2018.
Applicants: NEXUS Gas Transmission, LLC.

Description: § 4(d) Rate Filing:
NEXUS Negotiated Rate Agreements
First Year of Service—Compliance Filing.
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


Accession Number: 20180918–5008. Comments Due: 5 p.m. ET 10/1/18. The filings are accessible in the Commission’s eLibrary system by clicking on the links or querying the docket number.

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.

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: EC18–135–000. Applicants: 64KT 8me LLC. Description: Second Supplement to August 9, 2018 Application for Authorization under Section 203 of the Federal Power Act, et al. of 64KT 8me LLC. Filed Date: 9/18/18. Accession Number: 20180918–5105. Comments Due: 5 p.m. ET 9/25/18.


Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG18–128–000. Applicants: Cricket Valley Energy Center, LLC.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the “eFiling” link at http://www.ferc.gov. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at http://www.ferc.gov, using the “eLibrary” link and is available for review in the Commission’s Public Reference Room in Washington, DC. There is an “eSubscription” link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on October 10, 2018.


Nathaniel J. Davis, Sr.,
Deputy Secretary.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Supplemental Filing: Reilly, Lawrence J.

Take notice that on September 19, 2018, Lawrence J. Reilly filed a Supplement to the September 7, 2018 filed Application for Approval of Interlocking Position, pursuant to section 305(b) of the Federal Power Act, 16 U.S.C. 825d(b) (2012), and section 45.8 of the Federal Energy Regulatory Commission’s (Commission) regulations, 18 CFR 45.8 (2018).

Any person desiring to intervene or protest this filing must file in accordance with Rules 211 and 214 of the Commission’s Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date of the second supplement, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.
ENVIRONMENTAL PROTECTION AGENCY


Agency Information Collection Activities: Proposed Renewal of an Existing Collection (EPA ICR No. 2451.02); Comment Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA), this document announces that EPA is planning to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICR, entitled: “Soil and Non-Soil Fumigant Risk Mitigation” and identified by EPA ICR No. 2451.02 and OMB Control No. 2070–0197, represents the renewal of an existing ICR that is scheduled to expire on April 30, 2019. Before submitting the ICR to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection that is summarized in this document. The ICR and accompanying material are available in the docket for public review and comment.

DATES: Comments must be received on or before November 26, 2018.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2018–0423 by one of the following methods:

FOR FURTHER INFORMATION CONTACT: Nathaniel J. Davis, Sr., Deputy Secretary. [FR Doc. 2018–20893 Filed 9–25–18; 8:45 am]

BILLING CODE 6717–01–P


Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2018–20893 Filed 9–25–18; 8:45 am]
numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: In completing reviews of several soil and non-soil fumigants pursuant to section 4(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the EPA determined that these fumigants are eligible for reregistration only if specific risk mitigation measures, as outlined in Reregistration Eligibility Decisions for the chemicals, are adopted and adequately implemented. This ICR addresses the paperwork activities that both users and registrants of these specific soil and non-soil fumigants must perform in order to comply with the required risk mitigation measures.

Without the complete suite of measures, these soil and non-soil fumigant chemicals do not meet the requirements to be eligible for registration or reregistration under FIFRA. The programs and activities represented in this ICR are the result of the Agency exercising the authority of section 3(c)(2)(B) or section 3(c)(5) of FIFRA, which authorizes EPA to require pesticide registrants to generate and submit data to the Agency, when such data are needed to maintain an existing registration of a pesticide. Due to the high benefits of these chemicals, there could be significant economic impact if these fumigant products are no longer available.

Burden statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2.9 hours per response. Burden is defined in 5 CFR 1320.12. EPA will issue another notice and approval pursuant to 5 CFR 1320.12. EPA will issue another Federal Register document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of this ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under FOR FURTHER INFORMATION CONTACT.

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another Federal Register document pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the person listed under FOR FURTHER INFORMATION CONTACT.

Authority: 44 U.S.C. 3501 et seq.

Dated: September 13, 2018.

Charlotte Bertrand,
Acting Principal Deputy Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2018–20957 Filed 9–25–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[40–601–0025; FRL–9982–51–OAR]

Proposed Information Collection Request: Comment Request; National Emission Standards for Hazardous Air Pollutants for Asbestos (40 CFR Part 61, Subpart M) (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), “National Emission Standard for Hazardous Air Pollutants (NESHAP) for Asbestos (40 CFR part 61, subpart M) (Renewal)” (EPA ICR No. 0111.15, OMB Control No. 2060–0101) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a second notice requesting comment on the proposed extension of the ICR, which is currently approved through March 31, 2019. The burden in this notice includes changes in reporting and recordkeeping resulting from a recent action on an alternative work practice and a planned change to allow electronic reporting for notifications. 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: Comments must be submitted on or before November 26, 2018.


The 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:
Susan Fairchild, Sector Policies and Programs Division (Mail Code D243–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5167; fax number: (919) 541–4991; email address: Fairchild.susan@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 https://www.regulations.gov or in person at the EPA Docket Center. EPA WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about the EPA’s public docket, visit http://www.epa.gov/dockets.

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) 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; (ii) 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; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) 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. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, the EPA will issue another Federal Register notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: For the Asbestos NESHAP ICR, owners and operators of affected facilities are required to comply with reporting and recordkeeping requirements for the general provisions of 40 CFR part 61, subpart M, as well as the applicable specific standards.

This includes submitting initial notifications, performance tests, and periodic reports and results, maintaining records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. These reports are used by the EPA to determine compliance with the standard.

Form Numbers: None.
Respondents/affected entities:
Owners/operators of demolition and renovation activities: asbestos waste disposal; asbestos milling, manufacturing, and fabricating facilities; use of asbestos on roadways; asbestos waste converting facilities; and use of asbestos insulation and sprayed-on materials.

Respondent’s obligation to respond: Mandatory (40 CFR part 61, subpart M).

Estimated number of respondents: 9,575 (total).
Frequency of response: Initially, occasionally, quarterly, and semiannually.
Total estimated burden: 261,000 hours (per year). Burden is defined at 5 CFR 1320.03(b).
Total estimated cost: $26,300,000, includes no annualized capital or operation and maintenance costs.

Changes in Estimates: The burden in this document includes changes in reporting and recordkeeping resulting from a recent action on an alternative work practice and a planned change to allow electronic reporting for notifications. There is a decrease of 30,778 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to the movement from paper to electronic submissions.

The EPA will also explain the financial benefits of WIFIA credit assistance and provide high-level information about the benefits and flexibilities of closed loans.

Members of the public are invited to participate in the session as capacity allows.

SUPPLEMENTARY INFORMATION: Under WIFIA, the EPA will provide loans and loan guarantees for water infrastructure of national or regional significance. WIFIA was signed into law on June 11, 2014 as Public Law 113–121. The EPA will provide an overview of the program’s statutory and eligibility requirements, application and selection process, and creditworthiness assessment. The EPA will also explain the financial benefits of WIFIA credit assistance and provide high-level information about the benefits and flexibilities of closed loans.
FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Partial Closure of Federal Accounting Standards Advisory Board Meeting

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act, as amended (5 U.S.C. App.), and the FASAB Rules Of Procedure, as amended in October 2010, notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) will be holding a partially closed meeting on December 19, 2018. The Appointments Panel, a subcommittee of FASAB that makes recommendations to the sponsors regarding appointments for non-federal member positions, is expected to meet on December 19, 2018.

A portion of the meeting will likely need to be closed to the public in the event that matters covered by 5 U.S.C. 552b(c)(2) and (6) are discussed. Any such discussions will involve discussions that relate solely to internal personnel rules and practices of the sponsor agencies and the disclosure of information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy. Such discussions will be segregated into separate discussions so that a portion of each meeting will be open to the public.

Pursuant to section 10(d) of the Federal Advisory Committee Act (FACA), portions of advisory committee meetings may be closed to the public where the head of the agency to which the advisory committee reports determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code. The determination shall be in writing and shall contain the reasons for the determination. A determination has been made in writing by the U.S. Government Accountability Office, the U.S. Department of the Treasury, and the Office of Management and Budget, as required by section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. App., that such portions of the meetings may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code.

The listed meeting will be held in conjunction with a previously announced FASAB meeting. See 82 FR 57,751 (Dec. 7, 2017). Unless otherwise noted, FASAB meetings begin at 9 a.m. and conclude before 5 p.m. and are held at the U.S. Government Accountability Office (GAO) Building at 441 G St. NW in Room 7C13. Agendas and briefing materials will be available at http://www.fasab.gov/briefing-materials/ approximately one week before each meeting.

Any interested person may attend the meetings as an observer. Board discussion and reviews are open to the public except for those portions that are closed. GAO Building security requires advance notice of your attendance. If you wish to attend a FASAB meeting, please pre-register on our website at http://www.fasab.gov/pre-registration/ no later than 8 a.m. the Monday before the meeting to be observed.

FOR FURTHER INFORMATION CONTACT: Ms. Wendy M. Payne, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.


Wendy M. Payne.
Executive Director.

[FR Doc. 2018–20937 Filed 9–25–18; 8:45 am]

BILLING CODE 1510–02–P

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 the 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.: 201275.
Agreement Name: NBP/CNCo Pacific-Asia Slot Charter Agreement.
Filing Party: Conte Cicala; Clyde & Co.
Synopsis: The Agreement authorizes the parties to charter space on each other’s vessels between foreign ports and Pago Pago, American Samoa.
Proposed Effective Date: 9/13/2018.
Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/16284.

Agreement No.: 011075–079.
Agreement Name: MOL/NMCC/WLS/Glovis Space Charter Agreement.
Filing Party: Eric Jeffrey; Nixon Peabody.
Synopsis: The Agreement authorizes the parties to charter space to one another on an as needed, as available, basis for the carriage of vehicles and other Ro-Ro cargo in the trades between the United States and all foreign countries.
Proposed Effective Date: 10/27/2018.
Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/16284.

Agreement No.: 012179–002.
Agreement Name: Hoegh/Farrell Space Charter Agreement.
Parties: Farrell Lines Incorporated and Hoegh Lines (Farrell) AS.
Filing Party: Wayne Rohde; Cozen O’Connor.
Synopsis: The agreement authorizes Hoegh to charter space to one another on an as needed, as available, basis for the carriage of vehicles and other Ro-Ro cargo in the trades between the United States and all foreign countries.
Proposed Effective Date: 9/17/2018.
Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1332.

Agreement No.: 012179–002.
Agreement Name: Hoegh/Farrell Space Charter Agreement.
Parties: Farrell Lines Incorporated and Hoegh Lines (Farrell) AS.
Filing Party: Jeff Vogel; Cozen O’Connor.
Synopsis: The amendment adds in Sections 5.2 and 5.5 the ability for Hoegh to charter space to Farrell on its
The Agreement authorizes Dole Ocean Cargo Express, LLC and Crowley Latin America Services, LLC to charter space to CMA CGM/Maersk Line to charter space to CMA CGM on its TRIDENT/PAD2 service in the trade between ports on the Atlantic Coast of the United States and ports in Australia, New Zealand, Colombia and Panama. The parties request expedited review.

Proposed Effective Date: 11/3/2018.
Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/16297.


Rachel E. Dickon, Secretary.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Agency Information Collection Activities: Proposed Collection;
Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by November 26, 2018.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:
1. Electronically. You may send your comments electronically to http://www.regulations.gov. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.
2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see ADDRESSES).

CMS—10410 Medicaid Program; Eligibility Changes under the Affordable Care Act of 2010

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. The term “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 requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.
Information Collection
1. Type of Information Collection
Request: Extension of a currently approved collection; Title of Information Collection: Medicaid Program; Eligibility Changes under the Affordable Care Act of 2010; Use: The eligibility systems are essential to the goal of increasing coverage in insurance affordability programs while reducing administrative burden on states and consumers. The electronic transmission and automation of data transfers are key elements in managing the expected insurance affordability program caseload that started in 2014.

accomplishing the same work without these information collection requirements would not be feasible. Form Number: CMS–10410 (OMB control number 0938–1147); Frequency: Occasionally; Affected Public: Individuals or Households, and State, Local, and Tribal Governments; Number of Respondents: 25,500,096; Total Annual Responses: 25,500,333; Total Annual Hours: 21,276,302. (For policy questions regarding this collection contact Stephanie Bell at 410–786–0617).

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–20868 Filed 9–25–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2018–N–3306]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 2, 2018, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/ AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–3306. The docket will close on October 31, 2018. Submit either electronic or written comments on this public meeting by October 31, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 31, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of October 31, 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.

Comments received on or before October 18, 2018, will be provided to the committees. Comments received after that date will be taken into consideration by FDA. You may submit comments as follows:

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 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 No. FDA–2018–N–3306 for “Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” 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.” FDA 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.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0007]

Fee for Using a Material Threat Medical Countermeasure Priority Review Voucher in Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a material threat medical countermeasure (MCM) priority review voucher for fiscal year (FY) 2019. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to determine and collect material threat MCM priority review user fees for certain applications for review of human drug products when those applications use a material threat MCM priority review voucher. These vouchers are awarded to the applicants of material threat MCM applications that meet all of the requirements of this program upon FDA approval of such applications. The amount of the fee for using a material threat MCM priority review voucher is determined each FY based on the difference between the average cost incurred by FDA to review a human drug application designated as priority review in the previous FY, and the average cost incurred in the review of an application that is not subject to priority review in the previous FY. This notice establishes the material threat MCM priority review fee rate for FY 2019 and outlines the payment procedures for such fees.


SUPPLEMENTARY INFORMATION:

I. Background

Section 3086 of the Cures Act (Pub. L. 114–255) added section 565A to the FD&C Act (21 U.S.C. 360bb–4a). In section 565A of the FD&C Act, Congress encouraged development of material threat MCMs by offering additional incentives for obtaining FDA approval of such products. Under section 565A of the FD&C Act, the applicant of an eligible material threat MCM application (as defined in section 565A(a)(4)) shall receive a priority review voucher upon approval of the

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: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: kalyani.bhatt@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA’s website at https://www.fda.gov/Advisory-Committees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committees will discuss the efficacy, safety, and benefit-risk profile of new drug application (NDA) 211371, brexanolone 5 mg/mL intravenous injection, submitted by Sage Therapeutics, for the proposed indication of postpartum depression.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s website after the meeting. Background material is available at https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see ADDRESSES) on or before October 18, 2018, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 10, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 11, 2018.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaomaf@fda.hhs.gov or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require special accommodations due to a disability, please contact Kalyani Bhatt (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under Section 3086 of the Cures Act (Pub. L. 114–255) added section 565A to the FD&C Act, the applicant of such products. Under section 565A of the FD&C Act, the applicant of an eligible material threat MCM application (as defined in section 565A(a)(4)) shall receive a priority review voucher upon approval of the

The Food and Drug Administration (FDA or the Agency) is announcing the fee rate for using a material threat medical countermeasure (MCM) priority review voucher for fiscal year (FY) 2019. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to determine and collect material threat MCM priority review user fees for certain applications for review of human drug products when those applications use a material threat MCM priority review voucher. These vouchers are awarded to the applicants of material threat MCM applications that meet all of the requirements of this program upon FDA approval of such applications. The amount of the fee for using a material threat MCM priority review voucher is determined each FY based on the difference between the average cost incurred by FDA to review of a human drug application designated as priority review in the previous FY, and the average cost incurred in the review of an application that is not subject to priority review in the previous FY. This notice establishes the material threat MCM priority review fee rate for FY 2019 and outlines the payment procedures for such fees.


SUPPLEMENTARY INFORMATION:

I. Background

Section 3086 of the Cures Act (Pub. L. 114–255) added section 565A to the FD&C Act (21 U.S.C. 360bb–4a). In section 565A of the FD&C Act, Congress encouraged development of material threat MCMs by offering additional incentives for obtaining FDA approval of such products. Under section 565A of the FD&C Act, the applicant of an eligible material threat MCM application (as defined in section 565A(a)(4)) shall receive a priority review voucher upon approval of the

Billingle Code 4164–01–P
material threat MCM application. The recipient of a material threat MCM priority review voucher may either use the voucher for a future human drug application submitted to FDA under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), or transfer (including by sale) the voucher to another party. The voucher may be transferred (including by sale) repeatedly until it ultimately is used for a human drug application submitted to FDA under section 505(b)(1) of the FD&C Act or section 351(a) of the Public Health Service Act.

A priority review is a review conducted with a Prescription Drug User Fee Act (PDUFA) goal date of 6 months after the receipt or filing date, depending on the type of application. Information regarding PDUFA goals is available at https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf.

The applicant that uses a material threat MCM priority review voucher is entitled to a priority review of its eligible human drug application, but must pay FDA a material threat MCM priority review user fee in addition to any user fee required by PDUFA for the application. Information regarding the material threat MCM priority review voucher program is available at: https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm566498.htm.

This notice establishes the material threat MCM priority review fee rate for FY 2019 and outlines FDA’s procedures for payment of material threat MCM priority review user fees. This rate is effective on October 1, 2018, and will remain in effect through September 30, 2019.

II. Material Threat Medical Countermeasure Priority Review User Fee for FY 2019

FDA interprets section 565A(c)(2) of the FD&C Act as requiring that FDA determine the amount of the material threat MCM priority review user fee each fiscal year based on the difference between the average cost incurred by FDA in the review of a human drug application subject to priority review in the previous fiscal year, and the average cost incurred by FDA in the review of a human drug application that is not subject to priority review in the previous fiscal year.

A priority review is a review conducted with a PDUFA goal date of 6 months after the receipt or filing date, depending on the type of application. Under the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of the applications granted priority review status within this expedited timeframe. Normally, an application for a human drug product will qualify for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. An application that does not receive a priority designation receives a standard review. Under the PDUFA goals letter, FDA has committed to reviewing and acting on 90 percent of standard applications within 10 months of the receipt or filing date, depending on the type of application. A priority review involves a more intensive level of effort and a higher level of resources than a standard review.

As interpreted by FDA, section 565A of the FD&C Act requires that the fee amount should be based on the difference between the average cost incurred by the Agency in the review of a human drug application subject to a priority review in the previous fiscal year, and the average cost incurred by the Agency in the review of a human drug application not subject to a priority review in the previous fiscal year. FDA is setting a fee for FY 2019, which is to be based on standard cost data from the previous fiscal year, FY 2018. However, the FY 2018 submission cohort has not been closed out yet, thus the cost data for FY 2018 are not complete. The latest year for which FDA has complete cost data is FY 2017. Furthermore, because FDA has never tracked the cost of reviewing applications that get priority review as a separate cost subset, FDA estimated this cost based on other data that the Agency has tracked. FDA uses data that the Agency estimates and publishes on its website each year—standard costs for review. FDA does not publish a standard cost for “the review of a human drug application subject to priority review in the previous fiscal year.” However, we expect all such applications would contain clinical data. The standard cost application categories with clinical data that FDA publishes each year are: (1) New drug applications (NDAs) for a new molecular entity (NME) with clinical data and (2) biologics license applications (BLAs).

The standard cost worksheets for FY 2017 show standard costs of $5,340,560 for an NME NDA, and $4,596,936 for a BLA. Based on these standard costs, the total cost to review the 57 applications in these two categories in FY 2017 (31 NME NDAs with clinical data and 26 BLAs) was $285,077,688. (Note: These numbers exclude the President’s Emergency Plan for AIDS Relief NDAs; no investigational new drug review costs are included in this amount.)

Thirty-three of these applications (20 NDAs and 13 BLAs) received priority review, which would mean that the remaining 24 received standard reviews. Because a priority review compresses a review schedule that ordinarily takes 10 months into 6 months, FDA estimates that a multiplier of 1.67 (10 months ÷ 6 months) should be applied to non-priority review costs in estimating the effort and cost of a priority review as compared to a standard review. This multiplier is consistent with published research on this subject that supports a priority review multiplier in the range of 1.48 to 2.35 (Ref. 1). Using FY 2017 figures, the costs of a priority and standard review are estimated using the following formula:

\[33 \times 1.67 + (24 \times 1.67) = 285,077,688\]

where “\(\alpha\)” is the cost of a standard review and “\(\alpha \times 1.67\)” is the cost of a priority review. Using this formula, the cost of a standard review for NME NDAs and BLAs is calculated to be $3,603,561 (rounded to the nearest dollar) and the cost of a priority review for NME NDAs and BLAs is 1.67 times that amount, or $6,017,946 (rounded to the nearest dollar). The difference between these two cost estimates, or $2,414,386, represents the incremental cost of conducting a priority review rather than a standard review.

For the FY 2019 fee, FDA will need to adjust the FY 2017 incremental cost by the average amount by which FDA’s average costs increased in the 3 years prior to FY 2018, to adjust the FY 2017 amount for cost increases in FY 2018. That adjustment, published in the Federal Register on August 1, 2018 (see 83 FR 37504), setting FY 2019 PDUFA fees, is 1.7708 percent for the most recent year, not compounded.

Increasing the FY 2017 incremental priority review cost of $2,414,386 by 1.7708 percent (or 0.017708) results in an estimated cost of $2,457,140 (rounded to the nearest dollar). This is the material threat MCM priority review user fee amount for FY 2019 that must be submitted with a priority review voucher for a human drug application in FY 2019, in addition to any PDUFA fee that is required for such an application.

III. Fee Schedule for FY 2019

The fee rate for FY 2019 is set out in table 1:
TABLE 1—MATERIAL THREAT MEDICAL COUNTERMEASURE PRIORITY REVIEW SCHEDULE FOR FY 2019

<table>
<thead>
<tr>
<th>Fee category</th>
<th>Fee rate for FY 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application submitted with a material threat MCM priority review voucher in addition to the normal PDUFA fee</td>
<td>$2,457,140</td>
</tr>
</tbody>
</table>

IV. Implementation of Material Threat Medical Countermeasure Priority Review User Fee

Under section 565A(c)(4)(A) of the FD&C Act, the priority review user fee is due upon submission of a human drug application for which the priority review voucher is used. Section 565A(c)(4)(B) of the FD&C Act specifies that the application will be considered incomplete if the priority review user fee and all other applicable user fees are not paid in accordance with FDA payment procedures. In addition, section 565A(c)(4)(C) specifies that FDA may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section of the FD&C Act.

The material threat MCM priority review fee established in the new fee schedule must be paid for any application that is received on or after October 1, 2018, and submitted with a priority review voucher. This fee must be paid in addition to any other fee due under PDUFA, Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, credit card, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). Secure electronic payments can be submitted using the User Fees Payment Portal at https://userfees.fda.gov/pay. (Note: Only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, select “Pay Now” to be redirected to https://www.pay.gov/public/home. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a web-based payment application for online electronic payment. The Pay.gov feature is available on the FDA website after the user fee ID number is generated.

If paying with a paper check, the user fee identification (ID) number should be included on the check, followed by the words “Material Threat Medical Countermeasure Priority Review.” All paper checks must be in U.S. currency from a U.S. bank made payable and mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000. If checks are sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.) The FDA post office box number (P.O. Box 979107) must be written on the check. If needed, FDA’s tax identification number is 53–0196965.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. The account information is as follows: U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Number: 75060099, Routing Number: 021030004, SWIFT: FRNYUS33.

V. Reference

The following reference is on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is not available electronically at https://www.regulations.gov as this reference is copyright protected. FDA has verified the website address, as of the date this document publishes in the Federal Register, but websites are subject to change over time.


Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2018–20910 Filed 9–25–18; 8:45 am]
BILING CODE 4164–01–P
has submitted the following proposed collection of information to OMB for review and clearance.


**OMB Control Number 0910–0800—Extension**

This information collection supports Agency implementation of the Drug Quality and Security Act (Pub. L. 113–54), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding new section 503B (21 U.S.C. 353b). Under section 503B(b) of the FD&C Act, a compounding outsourcing facility must maintain records of all adverse events as specified in the guidance and that preparing and submitting this information will take approximately 1.1 hours per registrant (“Average Burden per Response” in table 1). Likewise, we estimate that annually 55 outsourcing facilities (“Number of Respondents” in table 2) will maintain records of adverse events as specified in the guidance and that preparing and maintaining the records will take approximately 16 hours per recordkeeper (“Average Burden per Recordkeeping” in table 2).

**TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹**

<table>
<thead>
<tr>
<th>Compounding outsourcing facility</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>Submission of adverse event reports’ including copy of labeling and other information as described in the guidance</td>
<td>55</td>
<td>1</td>
<td>55</td>
<td>1.1</td>
<td>61</td>
</tr>
</tbody>
</table>

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

**TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹**

<table>
<thead>
<tr>
<th>Type of recordkeeping</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records of adverse events, including records of efforts to obtain the data elements for each adverse event report</td>
<td>55</td>
<td>1</td>
<td>55</td>
<td>16</td>
<td>880</td>
</tr>
</tbody>
</table>

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

This is the first extension of the information collection and we have retained the currently approved burden estimate. Based on our review of Agency data, we estimate that annually 55 outsourcing facilities (“Number of Respondents” and “Total Annual Responses” in table 1) will submit adverse event reports to FDA as specified in the guidance and that preparing and submitting this information will take approximately 1.1 hours per registrant (“Average Burden per Response” in table 1). Likewise, we estimate that annually 55 outsourcing facilities (“Number of Recordkeepers” in table 2) will maintain records of adverse events as specified in the guidance and that preparing and maintaining the records will take approximately 16 hours per recordkeeper (“Average Burden per Recordkeeping” in table 2).


Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018–20909 Filed 9–25–18; 8:45 am]
BILLING CODE 4164–01–P
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
[Docket No. FDA–2018–N–0007]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2019  

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2019 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2018 (ADUFA IV), establishes four revenue amounts established for years (21 U.S.C. 379j–12(c) and (g)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: Revenue from application fees shall be 20 percent of total fee revenue; revenue from product fees shall be 27 percent of total fee revenue; revenue from establishment fees shall be 26 percent of total fee revenue; and revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)).

For FY 2019, the animal drug user fee rates are: $449,348 for an animal drug application; $224,674 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 366b(d)(4)); $10,747 for an annual product fee; $146,038 for an annual establishment fee; and $125,990 for an annual sponsor fee. FDA will issue invoices for FY 2019 product, establishment, and sponsor fees by December 31, 2018, and payment will be due by January 31, 2019. The application fee rates are effective for applications submitted on or after October 1, 2018, and will remain in effect through September 30, 2019. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the Animal Drug User Fee program (ADUFA program).

II. Revenue Amount for FY 2019

A. Statutory Fee Revenue Amounts

ADUFA IV, Title I of Public Law 115–234, specifies that the aggregate fee revenue amount for FY 2019 for all animal drug user fee categories is $30,331,000 (rounded to the nearest thousand dollars) (21 U.S.C. 379j–12(b)(1)(A)).

B. Inflation Adjustment to Fee Revenue Amount

The fee revenue amounts established in ADUFA IV for FY 2020 and subsequent fiscal years are subject to an inflation adjustment (21 U.S.C. 379j–12(c)(2)).

ADUFA IV specifies that the annual fee revenue amount is to be adjusted using two separate adjustment factors—Personal and Benefits (PC&B) costs and one for non-PC&B costs (21 U.S.C. 379j–12(c)(2)(A)(iii) and (iii)). The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years.

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy: annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total FDA costs. Because the adjustment for inflation does not take effect until FY 2020, FDA will not adjust the FY 2019 fee revenue amount for inflation.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The fee revenue amounts established in ADUFA IV for FY 2020 and subsequent fiscal years are subject to adjustment to account for changes in FDA’s review workload. A workload adjustment will be applied to the inflation adjusted fee revenue amount (21 U.S.C. 379j–12(c)(3)).

ADUFA IV specifies that FDA shall calculate the weighted average of the change in the total number of each of the five types of applications and submissions specified in the workload adjustment provision (animal drug applications, supplemental animal drug applications for which data with respect to safety or efficacy are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions). Because the adjustment for workload does not take effect until FY 2020, FDA will not adjust the FY 2019 fee revenue amount for workload changes.

D. Reduction of Workload-Based Increase by Amount of Certain Excess Collections

Under section 740(c)(3)(B) of the FD&C Act, for fiscal years 2021 through 2023, if application of the workload adjustment increases the amount of fee revenues established for the fiscal year, as adjusted for inflation, the fee revenue increase will be reduced by the amount of any excess collections for the second preceding fiscal year, up to the amount of the fee revenue increase. Since this provision will not take effect until FY 2023.

FOR FURTHER INFORMATION CONTACT: Visit FDA’s website at http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, Lisa.Kable@fda.hhs.gov.

For general questions, you may also email the Center for Veterinary Medicine (CVM) at: cvmadufa@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 740 of the FD&C Act (21 U.S.C. 379j–12) establishes four different types of user fees: (1) Fees for certain types of animal drug applications and supplements; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions (21 U.S.C. 379j–12(a)). When certain conditions are met, FDA will waive or reduce fees (21 U.S.C. 379j–12(d)).

For FY 2019 through FY 2023, the FD&C Act establishes aggregate yearly base revenue amounts for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts established for years after FY 2019 are subject to adjustment for inflation and workload, and for excess collections to reduce workload-based increases or collection shortfalls after FY 2020 (21 U.S.C. 379j–12(c) and (g)). Fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: Revenue from application fees shall be 20 percent of total fee revenue; revenue from product fees shall be 27 percent of total fee revenue; revenue from establishment fees shall be 26 percent of total fee revenue; and revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)).

For FY 2019, the animal drug user fee rates are: $449,348 for an animal drug application; $224,674 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 366b(d)(4)); $10,747 for an annual product fee; $146,038 for an annual establishment fee; and $125,990 for an annual sponsor fee. FDA will issue invoices for FY 2019 product, establishment, and sponsor fees by December 31, 2018, and payment will be due by January 31, 2019. The application fee rates are effective for applications submitted on or after October 1, 2018, and will remain in effect through September 30, 2019. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the Animal Drug User Fee program (ADUFA program).

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The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy: annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total FDA costs. Because the adjustment for inflation does not take effect until FY 2020, FDA will not adjust the FY 2019 fee revenue amount for inflation.

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ADUFA IV specifies that FDA shall calculate the weighted average of the change in the total number of each of the five types of applications and submissions specified in the workload adjustment provision (animal drug applications, supplemental animal drug applications for which data with respect to safety or efficacy are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions). Because the adjustment for workload does not take effect until FY 2020, FDA will not adjust the FY 2019 fee revenue amount for workload changes.

D. Reduction of Workload-Based Increase by Amount of Certain Excess Collections

Under section 740(c)(3)(B) of the FD&C Act, for fiscal years 2021 through 2023, if application of the workload adjustment increases the amount of fee revenues established for the fiscal year, as adjusted for inflation, the fee revenue increase will be reduced by the amount of any excess collections for the second preceding fiscal year, up to the amount of the fee revenue increase. Since this provision will not take effect until FY 2023.
2021, FDA will not reduce the FY 2019 fee revenue amount for excess collections.

E. Recovery of Collection Shortfalls

Under section 740(g)(5)(A) of the FD&C Act, for FY 2021, the amount of fees otherwise authorized to be collected shall be increased by the amount, if any, by which the amount collected and appropriated for FY 2019 falls below the amount of fees authorized for FY 2019. For FY 2022, the amount of fees otherwise authorized to be collected shall be increased by the amount, if any, by which the amount collected and appropriated for FY 2020 falls below the amount of fees authorized for FY 2020. For FY 2023, the amount of fees otherwise authorized to be collected shall be increased by the cumulative amount, if any, by which the amount collected and appropriated for fiscal years 2021 and 2022 (including estimated collections for FY 2022) falls below the cumulative amount of fees authorized for those 2 fiscal years.

Because the recovery of collection shortfalls does not take effect until FY 2021, FDA will not adjust the FY 2019 fee revenue amount for the recovery of collection shortfalls.

F. Reduction of Shortfall-Based Fee Increase by Prior Year Excess Collections

Under section 740(g)(5)(B) of the FD&C Act, where FDA’s calculations under section 740(g)(5)(A) result in an increase for that fiscal year to recover a collection shortfall, FDA must reduce the increase by the amount of any excess collections for preceding fiscal years (after fiscal year 2018) that have not already been applied for purposes of reducing workload-based fee increases. Because the recovery of collection shortfalls does not take effect until FY 2021, FDA will not adjust the FY 2019 fee revenue amount for the reduction of shortfall-based fee increases by prior year excess collections.

G. FY 2019 Fee Revenue Amounts

ADUFA IV specifies that the revenue amount of $30,331,000 (rounded to the nearest thousand dollars) for FY 2019 is to be divided as follows: 20 percent, or a total of $6,066,200, is to come from application fees; 27 percent, or a total of $8,189,370, is to come from product fees; 26 percent, or a total of $7,886,060, is to come from establishment fees; and 27 percent, or a total of $8,189,370, is to come from sponsor fees (21 U.S.C. 379j-12(b)).

III. Application Fee Calculations for FY 2019

A. Application Fee Revenues and Numbers of Fee-Paying Applications

Each person that submits an animal drug application or a supplemental animal drug application shall be subject to an application fee, with limited exceptions (see 21 U.S.C. 379j–12(a)(1)). The term “animal drug application” means an application for approval of any new animal drug submitted under section 512(b)(1) or an application for conditional approval of a new animal drug submitted under section 571 of the FD&C Act (21 U.S.C. 360ccc) (see section 739 of the FD&C Act (21 U.S.C. 379j–11)). As the expanded definition of “animal drug application” includes applications for conditional approval submitted under section 571 of the FD&C Act, such applications are now subject to ADUFA fees, except that fees may be waived if the drug is intended solely to provide for a minor use or minor species (MUMS) indication (see 21 U.S.C. 379j–12(d)(1)(D)).

Prior to ADUFA IV, FDA only had authority to grant conditional approval for drugs intended for a MUMS indication. Under ADUFA IV, FDA retains authority to grant conditional approval for drugs intended for MUMS indications but also will be able to grant conditional approval for certain drugs not intended for a MUMS indication provided certain criteria are met. Beginning with FY 2019, ADUFA IV provides an exception from application fees for animal drug applications submitted under section 512(b)(1) of the FD&C Act if the application is submitted by a sponsor who previously applied for conditional approval under the non-MUMS pathway of section 571 for the same product and paid an application fee at the time they applied for conditional approval. The purpose of this exception is to prevent sponsors of conditionally approved products from having to pay a second application fee at the time they apply for full approval of their products under section 512(b)(1) of the FD&C Act, provided the sponsor’s application for full approval is filed consistent with the timeframes established in section 571(h) of the FD&C Act.

A “supplemental animal drug application” is defined as a request to the Secretary of Health and Human Services (Secretary) to approve a change in an animal drug application that has been approved, or a request to the Secretary to approve a change to an application approved under section 512(c)(2) of the FD&C Act for which data with respect to safety or effectiveness are required (21 U.S.C. 379j–11(2)). The application fees are to be set so that they will generate $6,066,200 in fee revenue for FY 2019.

To set animal drug application fees and supplemental animal drug application fees to realize $6,066,200, FDA must first make some assumptions about the number of fee-paying applications and supplements the Agency will receive in FY 2019.

The Agency knows the number of applications that have been submitted in previous years, which fluctuates annually. In estimating the fee revenue to be generated by animal drug application fees in FY 2019, FDA is assuming that the number of applications for which fees will be paid in FY 2019 will equal the average number of submissions over the 5 most recent completed years of the ADUFA program (FY 2013 to FY 2017).

Over the 5 most recent completed years, the average number of animal drug applications that would have been subject to the full fee was 7.2. Over this same period, the average number of supplemental applications for which safety or effectiveness data are required and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that would have been subject to half of the full fee was 12.6.

B. Application Fee Rates for FY 2019

FDA must set the fee rates for FY 2019 so that the estimated 7.2 applications for which the full fee will be paid and the estimated 12.6 supplemental applications for which safety or effectiveness data are required and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act for which half of the full fee will be paid will generate a total of $6,066,200. To generate this amount, the fee for an animal drug application, rounded to the nearest dollar, will have to be $4,493,348, and the fee for a supplemental animal drug application for which safety or effectiveness data are required and for applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act will have to be $2,244,674.
IV. Product Fee Calculations for FY 2019

A. Product Fee Revenues and Numbers of Fee-Paying Products

The animal drug product fee must be paid annually by the person named as the applicant in a new animal drug application or supplemental new animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360) and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003 (21 U.S.C. 379–12(a)(2)). The term "animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved (21 U.S.C. 379–11(3)).

The product fees are to be set so that they will generate $8,189,370 in fee revenue for FY 2019.

To set animal drug product fees to realize $8,189,370, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2019. FDA developed data on all animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. As of June 2018, FDA estimates that there are a total of 786 products submitted for listing by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA estimates that a total of 786 products will be subject to this fee in FY 2019.

In estimating the fee revenue to be generated by animal drug product fees in FY 2019, FDA is assuming that 3 percent of the products invoiced, or 24, will not pay fees in FY 2019 due to fee waivers and reductions. FDA has kept this estimate at 3 percent this year, based on historical data over the past 5 completed years of the ADUFA program.

Accordingly, the Agency estimates that a total of 762 (786 minus 24) products will be subject to product fees in FY 2019.

B. Product Fee Rates for FY 2019

FDA must set the fee rates for FY 2019 so that the estimated 762 products that pay fees will generate a total of $8,189,370. To generate this amount will require the fee for an animal drug product, rounded to the nearest dollar, to be $10,747.

V. Establishment Fee Calculations for FY 2019

A. Establishment Fee Revenues and Numbers of Fee-Paying Establishments

The animal drug establishment fee must be paid annually by the person who: (1) Owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act; (3) had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the fiscal year (see 21 U.S.C. 379j–12(a)(3)). An establishment subject to animal drug establishment fees is assessed only once such fee per fiscal year. The term “animal drug establishment’’ is defined as a foreign or domestic place of business at one general physical location, consisting of one or more buildings, all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form (21 U.S.C. 379j–11(4)). The establishment fees are to be set so that they will generate $7,886,060 in fee revenue for FY 2019.

To set animal drug establishment fees to realize $7,886,060, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2019. FDA developed data on all animal drug establishments and matched this to the list of all persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. As of June 2018, FDA estimates that there are a total of 54 establishments owned or operated by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA believes that 60 establishments will be subject to this fee in FY 2019.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2019, FDA is assuming that 60 percent of the establishments invoiced, or six, will not pay fees in FY 2019 due to fee waivers and reductions. FDA has kept this estimate at 60 percent this year, based on historical data over the past 5 completed years. Accordingly, the Agency estimates that a total of 54 establishments (60 minus 6) will be subject to establishment fees in FY 2019.

B. Establishment Fee Rates for FY 2019

FDA must set the fee rates for FY 2019 so that the fees paid for the estimated 54 establishments will generate a total of $7,886,060. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest dollar, to be $146,038.

VI. Sponsor Fee Calculations for FY 2019

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The animal drug sponsor fee must be paid annually by each person who: (1) Is named as the applicant in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive and (2) had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003 (see 21 U.S.C. 379j–11(6) and 379j–12(a)(4)). An animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–12(a)(4)). The sponsor fees are to be set so that they will generate $8,189,370 in fee revenue for FY 2019.

To set animal drug sponsor fees to realize $8,189,370, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2019. FDA estimates that a total of 196 sponsors will meet this definition in FY 2019.

In estimating the fee revenue to be generated by animal drug sponsor fees in FY 2019, FDA is assuming that 67 percent of the sponsors invoiced, or 131, will not pay sponsor fees in FY 2019 due to fee waivers and reductions. FDA has kept this estimate at 67 percent this year, based on historical data over the past 5 completed years of the ADUFA program. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2019.

Accordingly, the Agency estimates that a total of 65 sponsors (196 minus 131) will be subject to and pay sponsor fees in FY 2019.

B. Sponsor Fee Rates for FY 2019

FDA must set the fee rates for FY 2019 so that the estimated 65 sponsors that
pay fees will generate a total of $8,189,370. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest dollar, to be $125,990.

VIII. Fee Waiver or Reduction; Exemption From Fees

A. Barrier to Innovation Waivers

Under section 740(d)(1)(A) of the FD&C Act, an animal drug applicant may qualify for a waiver or reduction of one or more ADUFA fees if the fee would present a significant barrier to innovation because of limited resources available to the applicant or due to other circumstances. FDA CVM’s guidance for industry (GFI) #170, entitled “Animal Drug User Fees and Fee Waivers and Reductions,” states that for purposes of determining whether to grant a barrier to innovation waiver or reduction of ADUFA fees on financial grounds, FDA has determined an applicant with financial resources of less than $20,000,000 (including the financial resources of the applicant’s affiliates), adjusted annually for inflation, has limited resources available. Using the CPI for urban consumers (U.S. city average; not seasonally adjusted; all items; annual index), the inflation-adjusted level for FY 2019 will be $20,742,100; this level represents the financial resource ceiling that will be used to determine if there are limited resources available to an applicant requesting a Barrier to Innovation waiver on financial grounds for FY 2019 in addition to the criteria requiring the product to be innovative.

B. Exemptions From Fees

The types of fee waivers and reductions that applied last fiscal year still exist for FY 2019. However, two new exemptions from fees were established by ADUFA IV, as follows: If an animal drug application, supplemental animal drug application, or investigational submission involves the intentional genomic alteration of an animal that is intended to produce a human medical product, any person who is the named applicant or sponsor of that application or submission will not be subject to sponsor, product, or establishment fees under ADUFA based solely on that application or submission (21 U.S.C. 379j–12(d)(4)(B)).

Fees will not apply to any person who not later than September 30, 2023, submits to CVM a supplemental animal drug application relating to a new animal drug application approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3) of the FD&C Act (21 U.S.C. 352(w)(3)), if that person otherwise would be subject to user fees under ADUFA based only on the submission of the supplemental application (21 U.S.C. 379j–12(d)(4)(A)).

IX. Procedures for Paying the FY 2019 Fees

A. Application Fees and Payment Instructions

The appropriate application fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA IV that is submitted on or after October 1, 2018. The payment must be made in U.S. currency by one of the following methods: Wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at https://userfees.fda.gov/pay, or the Pay.gov payment option is available to you after you submit a cover sheet. (Note: only full payments are accepted. No partial payments can be made online.) Once you search for and find your invoice, select “Pay Now” to be redirected to https://www.pay.gov/. Electronic payment options are based on the balance due. Payment by credit card is available only for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please write your application’s unique Payment Identification Number (PIN), beginning with the letters AD, on the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. When paying by wire transfer, the invoice number needs to be included; without the invoice number, the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a payment by wire transfer: U.S. Department of Treasury, TREAS NYFC, 33 Liberty St., New York, NY 10045. FDA Deposit Account Number: 75060009, U.S. Department of Treasury routing/transit

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1 CVM’s guidance for industry (GFI) #170 is located at: https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052494.pdf.
2 An animal drug establishment is subject to only one such fee each fiscal year.

### Table 1—FY 2019 Fee Rates

<table>
<thead>
<tr>
<th>Animal drug user fee category</th>
<th>Fee rate for FY 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Drug Application Fees: Animal Drug Application</td>
<td>$449,348</td>
</tr>
<tr>
<td>Supplemental Animal Drug Application for Which Safety or Effectiveness Data are Required or Animal Drug Application Subject to the Criteria Set Forth in Section 512(d)(4) of the FD&amp;C Act</td>
<td>224,674</td>
</tr>
<tr>
<td>Animal Drug Product Fee</td>
<td>10,747</td>
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<tr>
<td>Animal Drug Establishment Fee</td>
<td>146,038</td>
</tr>
<tr>
<td>Animal Drug Sponsor Fee</td>
<td>125,990</td>
</tr>
</tbody>
</table>

Note:

- An animal drug sponsor is subject to only one such fee each fiscal year.

Step Four—Please submit your application and a copy of the completed Animal Drug Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product, Establishment, and Sponsor Fees

By December 31, 2018, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2019 using this fee schedule. Payment will be due by January 31, 2019. FDA will issue invoices in November 2019 for any products, establishments, and sponsors subject to fees for FY 2019 that qualify for fees after the December 2018 billing.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–20911 Filed 9–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3552]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Cigarette Warnings

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on an experimental study of cigarette warnings that is being conducted in support of the graphic label statement provision of the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

DATES: Submit either electronic or written comments on the collection of information by November 26, 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 November 26, 2018. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 26, 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 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 No. FDA–2018–N–3552 for “Experimental Study of Cigarette Warnings.” 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
I. Background

The Tobacco Control Act (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act amends section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) (15 U.S.C. 1333) to require FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection 4(a)(1) of the FCLAA. Section 202(b) of the Tobacco Control Act further amends section 4 of the FCLAA by adding that the Secretary of Health and Human Services (Secretary), through notice and comment rulemaking, may adjust the text of any of the label requirements if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of tobacco products.

In the Federal Register of June 22, 2011 (76 FR 36628), FDA issued a final rule entitled “Required Warnings for Cigarette Packages and Advertisements,” which specified nine images to accompany new textual warning statements for cigarettes. Although the rule was scheduled to become effective 15 months after it was issued, a panel of the U.S. Court of Appeals of the District of Columbia held, on August 24, 2012, that the rule in its current form violated the First Amendment. In a letter to Congress on March 15, 2013, the Attorney General reported FDA’s intention to undertake research to support a new rulemaking consistent with the Tobacco Control Act. Various phases of research have been underway since 2013. The next phase of the research includes the study proposed here, which is an effort by FDA to collect data concerning responses to cigarette warnings placed on cigarette packages and advertisements for cigarettes.

The health risks associated with the use of cigarettes are significant and far-reaching. Cigarette smoking is the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year. Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined (Ref. 1). In addition to lung cancer, heart disease, and chronic obstructive pulmonary disease, smoking also causes numerous other serious health conditions including several types of cancer, premature birth, low birth weight, respiratory illnesses, clogged arteries, reduced blood flow, diabetes, and vision conditions such as age-related macular degeneration and cataracts (Ref. 2).

Approximately 37.8 million U.S. adults smoke cigarettes (Ref. 3) and 8.6 million Americans have at least one serious illness caused by smoking cigarettes (Ref. 4). Results from the 2016 National Survey on Drug Use and Health demonstrate that, each day in the United States, more than 2,300 youth under age 18 smoke their first cigarette, and nearly 400 youth become daily cigarette smokers (Ref. 5). If the current trajectory of smoking rates continues, 5.6 million children alive today will die prematurely as a result of smoking (Ref. 2). Providing the public with accurate information regarding the health consequences of cigarette use is critical in achieving FDA’s mission to protect the public health.

This Experimental Study of Cigarette Warnings is a voluntary online experiment. The purpose of the study is to assess whether new cigarette warnings increase understanding of the negative health consequences of cigarette smoking. The study will collect...
data from various groups of consumers, including adolescent current cigarette smokers aged 13 to 17 years, adolescent non-smokers who are susceptible to initiation of cigarette smoking aged 13 to 17 years, young adult current cigarette smokers and non-smokers aged 18 to 24 years, and older adult current cigarette smokers and non-smokers aged 25 years and older. The results will inform the Agency’s efforts to implement the mandatory graphic warning label statements as required by section 4(d) of FCLAA.

**Study Overview:** In this study, adolescent current cigarette smokers, adolescent non-smokers who are susceptible to initiation of cigarette smoking, young adult current cigarette smokers and non-smokers, and older adult current cigarette smokers and non-smokers will be recruited through the internet and screened through the internet will occur with 866 respondents (456 potential participants for the 2 pretests and 410 adolescents) identified and recruited through the internet panel of more than 1.2 million people and screened for inclusion into the study. Participants who meet the inclusion criteria will be randomized into 1 of 17 conditions. In each condition, respondents will view one cigarette warning. In the 16 treatment conditions, participants will view 1 graphic health warning, containing a warning statement accompanied by a concordant color graphic depicting the negative health consequences of smoking described in the statement. In the control condition, participants will be randomized to view one of the four current Surgeon General’s warnings, representing the current state of cigarette warnings in the United States. In all conditions, participants will view their assigned warnings both on a mock cigarette package and a mock cigarette advertisement, presented in a randomized order.

There will be three sessions. During Session 1, participants will complete a baseline assessment about their beliefs about the negative health consequences of cigarette smoking. Next, they will be exposed to the stimuli (i.e., the warning based on condition assignment) and complete a set of items assessing (a) if the information presented in the warning was new; (b) self-reported learning from the warning; (c) if the warning was easy to understand; (d) if the warning was perceived to be a fact or an opinion; (e) if the warning was informative; (f) if the warning grabbed their attention; and (g) if the warning made them think about the health risks of cigarette smoking. During Session 2 (1 to 2 days after Session 1), participants will be exposed to the same stimuli again (i.e., the warning based on condition assignment from Session 1), and complete a set of items assessing beliefs about the negative health consequences caused by cigarette smoking. During Session 3 (approximately 14 days after Session 2), participants will complete a delayed post-test on beliefs about the negative health consequences caused by cigarette smoking and items assessing recall of the warning.

Prior to the main data collection, 2 sequential pretests, each with 50 participants, will take place to ensure correct programming of Session 1 and to identify any issues with the study design and implementation.

Study outcomes include comparisons to assess the extent to which exposure to the graphic health warnings, relative to the text-only Surgeon General’s warnings, provide new information, increase self-reported learning, change beliefs about the negative health consequences of cigarette smoking, increase thinking about the risks of smoking, as well as the extent to which the warnings are informative, easy to understand, factual, attention grabbing, and recalled.

FDA estimates the burden of this collection of information as follows:

**TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN**

<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>Adult—Screener for pretest</td>
<td>456</td>
<td>1</td>
<td>456</td>
<td>0.03 hours (2 minutes)</td>
<td>14</td>
</tr>
<tr>
<td>Adult—Pretest</td>
<td>68</td>
<td>1</td>
<td>68</td>
<td>0.20 hours (12 minutes)</td>
<td>14</td>
</tr>
<tr>
<td>Adult—Screener for main data collection</td>
<td>51,054</td>
<td>1</td>
<td>51,054</td>
<td>0.03 hours (2 minutes)</td>
<td>1,532</td>
</tr>
<tr>
<td>Adult—Main data collection (3 sessions)</td>
<td>7,460</td>
<td>1</td>
<td>7,460</td>
<td>0.42 hours (25 minutes)</td>
<td>3,133</td>
</tr>
<tr>
<td>Total Adult Hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4,693</td>
</tr>
<tr>
<td>Adolescent—Screener for pretest</td>
<td>410</td>
<td>1</td>
<td>410</td>
<td>0.03 hours (2 minutes)</td>
<td>12</td>
</tr>
<tr>
<td>Adolescent—Pretest</td>
<td>32</td>
<td>1</td>
<td>32</td>
<td>0.20 hours (12 minutes)</td>
<td>6</td>
</tr>
<tr>
<td>Adolescent—Screener for main data collection</td>
<td>29,487</td>
<td>1</td>
<td>29,487</td>
<td>0.03 hours (2 minutes)</td>
<td>885</td>
</tr>
<tr>
<td>Adolescent—Main data collection (3 sessions)</td>
<td>2,300</td>
<td>1</td>
<td>2,300</td>
<td>0.42 hours (25 minutes)</td>
<td>966</td>
</tr>
<tr>
<td>Total Adolescent Hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,869</td>
</tr>
<tr>
<td>Total Burden Hours</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6,562</td>
</tr>
</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.

2 The hours per response are rounded to two decimal places.
recruited through the same internet panel as used for the pretests. Participants will complete the screener questionnaire through an email invitation. This brief screening will take an average of 2 minutes (0.03 hours) per respondent. If, based on this screening, participants qualify for the study, they will be directed to begin Session 1.

Recent national estimates of the numbers of adolescent current cigarette smokers, adolescents who are susceptible to initiation of cigarette smoking, young adult current cigarette smokers, and older adult current cigarette smokers informed the estimates of 14.6 percent qualification rate for adults and 7.8 percent qualification rate for adolescents. Applying these estimates and other assumptions from previous experience conducting similar studies to the number of adolescents and adults to be screened results in the desired sample size for the main data collection of 9,760 participants, of which 7,460 will be adults and 2,300 will be adolescents. The three sessions of the main data collection will take an average of 12 minutes (0.20 hours) for Session 1, 8 minutes (0.13 hours) for Session 2, and 5 minutes (0.08 hours) for Session 3, for a total of an estimated 25 minutes (0.42 hours) per respondent. The total estimated burden for the data collection is 6,561 hours (4,692 hours for adults + 1,869 hours for adolescents).

II. References

The following references are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov.


Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018-20913 Filed 9–25–18; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3504]

Tobacco Product Application Review; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled “Tobacco Product Application Review.” This meeting is intended to improve public understanding and provide FDA feedback on the policies and processes for submitting and reviewing tobacco product marketing applications, including the general scientific principles relevant to various application pathways, to assist those considering submitting marketing applications for tobacco products under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The 2-day public meeting will be held on October 22, 2018, from 8:30 a.m. to 4:30 p.m. and on October 23, 2018, from 8:30 a.m. to 3 p.m. Submit either electronic or written comments on this public meeting by December 7, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.


You may submit comments as follows. Please note that late, untimely filed comments may not be considered. The https://www.regulations.gov electronic filing system will accept electronic comments until 11:59 p.m. Eastern Time on December 7, 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 December 7, 2018.

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 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 No. FDA–2018–N–3504 for “Tobacco Product Application Review.” Received comments, 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/2015-23369.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 Fiskers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:
Darin Achilles, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 877–287–1373, email: ctpregulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public meeting to improve public understanding and provide FDA feedback on the policies and processes for submitting and reviewing tobacco product marketing applications, including the general scientific principles relevant to various application pathways, to assist those considering submitting marketing applications for tobacco products under the FD&C Act. FDA will present information about the tobacco product application review programs, including process improvements and observations that may inform further improvements in submissions and review processes. The meeting will include panels of FDA representatives, regulated industry representatives, and other stakeholders, and FDA will seek feedback from the public. This meeting is not intended to communicate any new policies or interpretations regarding tobacco product marketing applications and their review.

FDA expects that parties interested in attending this meeting include, but are not limited to, tobacco product manufacturers, including small business tobacco manufacturers, importers, distributors, wholesalers, and retailers; scientific and medical experts; Federal, State, and local government Agencies; and other interested stakeholders, such as academic researchers and public health organizations.

In addition to the public meeting, FDA is opening a docket as another mechanism to receive feedback on the tobacco product application review process. Timely comments are appreciated to help inform FDA’s efforts to continue to build an efficient product review program. FDA is open to receiving feedback and comments on all aspects of the product review process and is requesting specific comment on the following topics:

- Achieving greater efficiencies in review while continuing to protect public health
  - Improving application content
  - Streamlining review processes
  - Refining electronic submission systems
- Reviewing applications for products that are rendered “new” due to changes made to comply with a product standard
- Facilitating applicant consultation with FDA prior to submitting applications
  - Types of questions that would benefit from FDA feedback
  - Meeting request and package content
  - Process from meeting request through post-meeting minutes
- Transparent review process
  - Aspects that are highly transparent
  - Aspects that are not highly transparent
  - Approaches to increase transparency
- Clarity and utility of information provided by FDA to applicants
  - Means of communicating information to applicants
  - Information that is most useful to applicants
  - Timeliness of communication

II. Topics for Discussion at the Public Meeting

Topics to be addressed in the meeting include:

- An overview of the tobacco product marketing application types, including Substantial Equivalence Reports, Substantial Equivalence Exemption Requests, Premarket Tobacco Product Applications, and Modified Risk Tobacco Product Applications;
- Information required and that FDA recommends be included in a tobacco product marketing application;
- Administrative processes involved in the submission and review of a tobacco product marketing application;
- Other topics relevant to tobacco product marketing applications, including tobacco product master files, meeting requests, grandfathered tobacco product review, and environmental assessments.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please submit electronic registration requests at https://www.surveymonkey.com/r/FDACTPProductApplicationMeeting. Requests for registration must include the prospective attendee’s name, title, affiliation, and contact information.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting should register by 11:59 p.m. Eastern Time on October 5, 2018. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. If registration reaches maximum capacity, FDA will post a notice closing registration at https://www.fda.gov/TobaccoProducts/NewsEvents/default.htm.

If you need special accommodations because of disability, please email Workshop.CTPOS@fda.hhs.gov or call 1–877–287–1373 (Option 5) at least 7 days before the meeting.

Streaming Webcast of the Public Meeting: There will be a webcast for this public meeting. If you would like to attend the meeting via webcast, please submit electronic requests to register at https://www.surveymonkey.com/r/FDACTPProductApplicationMeeting. Requests for registration must include the prospective attendee’s name, title, affiliation, and contact information.
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2016–D–4317]

**Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities; Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.” Specifically, this guidance sets forth FDA’s policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities, and it describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals.

**DATES:** The announcement of the guidance is published in the Federal Register on September 26, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidelines at any time as follows:

**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 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 No. FDA–2016–D–4317 for “Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.” Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(3)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self- addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD, 301–796–3110.

**SUPPLEMENTARY INFORMATION:**

I. Background

FDA is announcing the availability of a guidance for industry entitled “Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities; Guidance for Industry.” In 2013, the Drug Quality and Security Act created a new section, 503B, of the FD&C Act (21 U.S.C. 353b), which describes a new category of compounds called outsourcing facilities. Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in...
an outsourcing facility to qualify for exemptions from the following three sections of the FD&C Act: 
- Section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning labeling with adequate directions for use);
- section 505 (21 U.S.C. 355) (concerning drug approval requirements); and

In contrast to section 503A (21 U.S.C. 353a), section 503B of the FD&C Act does not exclude radiopharmaceuticals. Therefore, FDA’s overall policies regarding section 503B apply to the compounding of radiopharmaceutical drug products. However, we have developed specific policies that apply only to the compounding of radiopharmaceuticals by outsourcing facilities using bulk drug substances and to the compounding of radiopharmaceuticals by outsourcing facilities that are essentially copies of approved drugs when such compounding is limited to minor deviations, as that term is defined in the guidance. FDA is also issuing this guidance in part to describe the conditions under which the Agency does not generally intend to take action for violations of sections 505 and 502(f)(1) of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals for human use.

Elsewhere in this issue of the Federal Register, FDA has announced the availability of a separate guidance document concerning compounding and repackaging of radiopharmaceuticals by State-licensed nuclear pharmacies, Federal facilities, and other facilities that are not registered as outsourcing facilities, entitled “Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.” In the Federal Register of December 29, 2016 (81 FR 96005), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on February 27, 2017. FDA received approximately three comments on the draft guidance. In response to the comments, FDA made changes to the guidance to clarify particular points. For example, the reference to the syringe as an example of primary packaging was deleted in response to a comment stating that a syringe containing a radiopharmaceutical should not be described as “primary packaging” for labeling purposes because of the unique risks associated with radioactive drug products. In addition, FDA made revisions to align language used in this guidance with language used in the guidance entitled “Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.”

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on “Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). Under the PRA, Federal Agencies must obtain approval from 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 and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Specifically, the guidance references registration, adverse event reporting, product reporting, and current good manufacturing practices (CGMP) requirements for outsourcing facilities. The collections of information for outsourcing facility registration have been approved under OMB control number 0910–0777 (79 FR 69839, November 24, 2014). The collections of information for adverse event reporting by outsourcing facilities have been approved under OMB control number 0910–0800 (80 FR 60917, October 8, 2015). The collections of information for electronic drug product reporting by outsourcing facilities have been approved under OMB control number 0910–0827 (82 FR 129, January 3, 2017).

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.
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.

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- 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–2016–D–2268 for “Insanitary Conditions at Compounding Facilities.” Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the revised draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled “Insanitary Conditions at Compounding Facilities.” Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(A)), a drug is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Drug products compounded under insanitary conditions could become contaminated and cause serious adverse events, including death, in patients. Although sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b) provide exemptions for compounded drugs from specified provisions of the FD&C Act if certain conditions are met, neither section provides an exemption from section 501(a)(2)(A) of the FD&C Act.

Any drug that is prepared, packed, or held under insanitary conditions is deemed to be adulterated under the FD&C Act, including drugs produced by a compounding facility. Since a 2012 fungal meningitis outbreak associated with injectable drug products that a pharmacy compounded and shipped to patients and health care providers across the country, the Agency has identified insanitary conditions at many of the compounding facilities that it has inspected, and numerous compounders have voluntarily recalled drug products intended to be sterile and temporarily or permanently ceased sterile operations because of these findings. FDA does not inspect the vast majority of compounding facilities in the United States because they generally do not register with FDA unless they are outsourcing facilities. Therefore, unless FDA receives a complaint, such as a report of a serious adverse event or visible contamination, the Agency is often not aware of these facilities, their conditions and practices, and potential problems with the quality and safety of their drug products. It is critical that compounding facilities identify and remediate any insanitary conditions at their facilities before the conditions result in drug contamination and patient injury.

In the Federal Register of August 4, 2016 (81 FR 51449), FDA announced the availability of a draft guidance for industry entitled, “Insanitary Conditions at Compounding Facilities.” The draft guidance provided examples of insanitary conditions that the Agency has observed at compounding facilities it has inspected and considers to be insanitary conditions. The draft guidance also described corrective actions that compounding facilities should take when they identify such conditions and the regulatory actions FDA may take in response to identified insanitary conditions. FDA received comments on the draft guidance including feedback from various stakeholders (e.g., physicians and pharmacies), particularly concerning the implications of the policies described in the draft guidance for physicians who prepare drugs in their offices. FDA is revising the draft guidance to address the stakeholders’ feedback and to provide further clarification on the insanitary conditions described in the guidance, as well as the actions FDA intends to take with respect to insanitary conditions. FDA is issuing this revised draft guidance to enable the public to further review and comment before finalization of FDA’s policies concerning insanitary conditions. We
expect that the guidance will help compounding facilities to identify insanitary conditions so that they can implement appropriate corrective actions, and will assist states in identifying insanitary conditions during their inspections of compounding facilities.

This revised draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on “Insanitary Conditions at Compounding Facilities.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the revised draft guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.


Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2016–20903 Filed 9–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4318]

Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled “Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.” This guidance sets forth FDA’s policy regarding compounding and repackaging of radiopharmaceuticals for human use by State-licensed nuclear pharmacies, Federal facilities, and other entities that hold a radioactive materials (RAM) license for medical use issued by the Nuclear Regulatory Commission (NRC) or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repack radiopharmaceuticals.

DATES: The announcement of the guidance is published in the Federal Register on September 26, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 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, Room 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–2016–D–4318 for “Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.” Received comments 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, Room 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993--
I. Background

FDA is announcing the availability of a guidance for industry entitled “Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.” Under current law, radiopharmaceuticals that are compounded by entities that are not registered with FDA as outsourcing facilities, and radiopharmaceuticals that are repackaged, are subject to all applicable provisions of the FD&C Act related to the production of drugs. Because Congress explicitly excluded radiopharmaceuticals from section 503A of the FD&C Act (21 U.S.C. 353a) (see section 503A(d)(2)),1 compounded radiopharmaceuticals are not eligible for the exemptions under section 503A from section 505 (21 U.S.C. 355) (concerning new drug approval requirements), section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements). In addition, the FD&C Act does not provide an exemption for repackaged radiopharmaceuticals.

FDA is issuing this guidance to describe the conditions under which the Agency generally does not intend to take action for violations of sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act when a State-licensed nuclear pharmacy, Federal facility, or other facility that is not an outsourcing facility and that holds a RAM license for medical use issued by the NRC or by an Agreement State.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.” It does not establish any rights or responsibilities for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information have been approved under OMB control number 0910–0858.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–20902 Filed 9–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3305]

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Allergenic Products Advisory Committee (APAC). The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on November 7, 2018, from 9 a.m. to 4 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002.

Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm. For those unable to attend in person, the meeting will also be webcast and will be available at the following link: https://collaboration.fda.gov/vrppac2018/.

FOR FURTHER INFORMATION CONTACT:
Serina Hunter-Thomas, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993–0002.

240–402–5771, serina.hunter-thomas@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s website at https://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee.
information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On November 7, 2018, the Center for Biologics Evaluation and Research’s APAC will meet in open session to discuss the use of challenge studies in the clinical development of allergenic products for the diagnosis and treatment of allergy due to aeroallergens. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s website after the meeting. Background material is available at https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: On November 7, 2018, from 9 a.m. to 4 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 31, 2018. Oral presentations from the public will be scheduled between approximately 12:30 p.m. to 1:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 23, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 24, 2018.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).


Leslie Kux, Associate Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT:
Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, Trang.Tran@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANDA 072112</td>
<td>Clorazepate Dipotassium Capsules, 3.75 milligrams (mg), 7.5 mg, and 15 mg.</td>
<td>Aurolife Pharma, LLC, 279 Princeton Hightstown Rd., East Windsor, NJ 08520. Workhardt Bio AG, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053. Septodont, Inc., c/o Arent Fox, LLP, 1717 K St. NW, Washington, DC 20006. Do.</td>
</tr>
<tr>
<td>ANDA 074863</td>
<td>Clemastine Fumarate Syrup, Equivalent to (EQ) 0.5 mg base/5 milliliters (mL).</td>
<td>Do.</td>
</tr>
<tr>
<td>ANDA 080925</td>
<td>Isocaine 3% (mepivacaine hydrochloride (HCl)) Injection USP, 3%.</td>
<td>Do.</td>
</tr>
<tr>
<td>ANDA 084048</td>
<td>Octocaine (lidocaine HCl and epinephrine) Injection USP, 2%; 0.01 mg/mL and 2%; 0.02 mg/mL.</td>
<td>Do.</td>
</tr>
<tr>
<td>ANDA 084697</td>
<td>Isocaine 2% (mepivacaine HCl and levonordefrin) Injection USP, 2%; 0.05 mg/mL.</td>
<td>Do.</td>
</tr>
<tr>
<td>ANDA 086033</td>
<td>Isosorbide Dinitrate Sublingual Tablets USP, 2.5 mg ....</td>
<td>Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.</td>
</tr>
<tr>
<td>ANDA 087504</td>
<td>Chloroquine Phosphate Tablets USP, EQ 150 mg base</td>
<td>Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.</td>
</tr>
</tbody>
</table>

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of October 26, 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 October 26, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.


Leslie Kux,
Associate Commissioner for Policy.

SUPPLEMENTARY INFORMATION:

FOR FURTHER INFORMATION CONTACT:

CVM at cvmagdufa@fda.hhs.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET No. FDA–2018–N–0007]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2019 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2018 (AGDUFA III), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2019.

FOR FURTHER INFORMATION CONTACT: Visit FDA’s website at https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm, or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, Lisa.Kable@fda.hhs.gov. For general questions, you may also email the Center for Veterinary Medicine (CVM) at cvmagdufa@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j–21) establishes three different types of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j–21(d)).

For FY 2019 through FY 2023, the FD&C Act establishes a yearly base revenue amount and percentages for each of these fee categories (21 U.S.C. 379j–21(b)). Base revenue amounts established for fiscal years after FY 2019 are subject to adjustment for inflation and workload. Workload increases will be adjusted for excess collections after FY 2020 (21 U.S.C. 379j–21(c)). The target revenue amounts for each fee category for FY 2019, are as follows: For application fees, the target revenue amount is $4,584,000; for product fees, the target revenue amount is $6,876,000; and for sponsor fees, the target revenue amount is $6,876,000.

For FY 2019, the generic new animal drug user fee rates are: $424,444 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $212,222 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4): $15,486 for each generic new animal drug product; $150,098 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $112,574 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $75,049 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2019 product and sponsor fees by December 31, 2018. These fees will be due by January 31, 2019. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2018, and will remain in effect through September 30, 2019. Applications will not be accepted for review until FDA has received full payment of related application fees and any other fees owed under the Animal Generic Drug User Fee program (AGDUFA program).

II. Revenue Amount for FY 2019

A. Statutory Fee Revenue Amounts

AGDUFA III, Title II of Public Law 115–234, specifies that the aggregate revenue amount for FY 2019 for all generic new animal drug user fee categories is $18,336,000 (rounded to the nearest thousand dollars) (21 U.S.C. 379j–21(b)(1)).

B. Inflation Adjustment to Fee Revenue Amount

AGDUFA III specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2020 and subsequent fiscal years, using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see 21 U.S.C. 379j–21(c)(2)). The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years. The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total FDA costs. Because the adjustment for inflation does not take effect until FY 2020, FDA will not adjust the FY 2019 fee revenue amount for inflation.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The fee revenue amounts established in AGDUFA III for FY 2020 and subsequent fiscal years are also subject to adjustment to account for changes in FDA’s review workload. A workload adjustment will be applied to the inflation adjusted fee revenue amount (21 U.S.C. 379j–21(c)(3)).

AGDUFA III specifies that FDA shall calculate the weighted average of the change in the total number of each of the four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions). Because the
adjustment for workload does not take effect until FY 2020, FDA will not adjust the FY 2019 fee revenue amount for workload changes.

D. Reduction of Workload-Based Increase by Amount of Certain Excess Collections

Under section 741(c)(3)(B) of the FD&C Act, for FYs 2021 through 2023, if application of the workload adjustment increases the amount of fee revenues established for the fiscal year, as adjusted for inflation, the fee revenue increase will be reduced by the amount of any excess collections, for the second preceding fiscal year, up to the amount of the fee revenue increase. Since this provision will not take effect until FY 2021, FDA will not reduce the FY 2019 fee revenue amount for excess collections.

E. FY 2019 Fee Revenue Amounts

AGDUFA III specifies that the revenue amount of $18,336,000 (rounded to the nearest thousand dollars) for FY 2019 is to be divided as follows: 25 percent, or a total of $4,584,000, is to come from application fees; 37.5 percent, or a total of $6,876,000, is to come from product fees; and 37.5 percent, or a total of $6,876,000, is to come from sponsor fees (21 U.S.C. 379j–21(b)).

III. Abbreviated Application Fee Calculations for FY 2019

A. Application Fee Revenues and Numbers of Fee-Paying Applications

Each person that submits an abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions (21 U.S.C. 379j–21(a)(1)). The term “abbreviated application for a generic new animal drug” means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) (21 U.S.C. 379j–21(k)(1)). The application fees are to be set so that they will generate $4,584,000 in fee revenue for FY 2019. To set fees for abbreviated applications for generic new animal drugs to realize $4,584,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2019.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates annually. FDA is making estimates and applying different assumptions for two types of full fee submissions: Original submissions of abbreviated applications for generic new animal drugs and “reactivated” submissions of abbreviated applications for generic new animal drugs. Any original submissions of abbreviated applications for generic new animal drugs that were received by FDA before July 1, 2008, were not assessed fees (21 U.S.C. 379j–21(a)(1)(A)). Some of these non-fee-paying submissions were later resubmitted on or after July 1 because the initial submission was not approved by FDA (i.e., FDA marked the submission as incomplete and requested additional non-administrative information) or because the original submission was withdrawn by the sponsor. Abbreviated applications for generic new animal drugs resubmitted on or after July 1, 2008, are subject to user fees. In this notice, FDA refers to these resubmitted applications as “reactivated” applications.

Also, under AGDUFA III, an abbreviated application for an animal generic drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug (21 U.S.C. 379j–21(a)(1)(C)(iii)).

Regarding original submissions of abbreviated applications for generic new animal drugs, FDA is assuming that the number of applications for which fees will be paid in FY 2019 will equal the average number of submissions over the five most recently completed years of the AGDUFA program (FY 2013–FY 2017).

The average number of original submissions of abbreviated applications for generic new animal drugs over the five most recently completed years is 9.2 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 3.2 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 10.8 anticipated full fees.

In prior years, FDA had estimated the number of reactivations of abbreviated applications for generic new animal drugs that had been originally submitted prior to July 1, 2008, and will include no provision for them in its fee estimates. Should such a submission be made, the submitter will be expected to pay the appropriate fee.

Based on the previous assumptions, FDA is estimating that it will receive a total of 10.8 fee-paying generic new animal drug applications in FY 2019 (9.2 original applications paying a full fee and 3.2 applications paying a half fee).

B. Application Fee Rates for FY 2019

FDA must set the fee rates for FY 2019 so that the estimated 10.8 abbreviated applications that pay the fee will generate a total of $4,584,000. To generate this amount, the fee for a generic new animal drug application will have to be $424,444 and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or $212,222.

IV. Generic New Animal Drug Product Fee Calculations for FY 2019

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360d) and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(a)(2)). The term “generic new animal drug” means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved (21 U.S.C. 379j–21(k)(6)). The product fees are to be set so that they will generate $6,876,000 in fee revenue for FY 2019.

To set generic new animal drug product fees to realize $6,876,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2019. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who FDA estimated would have an abbreviated new animal drug application or supplemental abbreviated application...
application pending after September 1, 2008. As of June 2018, FDA estimates a total of 448 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 448 products will be subject to this fee in FY 2019.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2019, FDA is estimating that one percent of the products invoiced, or four products, will qualify for minor use/minor species fee waiver (see 21 U.S.C. 379–21(d)). FDA has made this estimate at one percent this year, based on historical data over the past five completed years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 444 (448 minus 4) products will be subject to product fees in FY 2019.

B. Product Fee Rates for FY 2019

FDA must set the fee rates for FY 2019 so that the estimated 444 products that pay fees will generate a total of $6,876,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest dollar, to be $15,486.

V. Generic New Animal Drug User Fees

VI. Fee Schedule for FY 2019

The fee rates for FY 2019 are summarized in table 1.

<table>
<thead>
<tr>
<th>Generic new animal drug user fee category</th>
<th>Fee rate for FY 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)</td>
<td>$424,444</td>
</tr>
<tr>
<td>Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)</td>
<td>$212,222</td>
</tr>
<tr>
<td>Generic New Animal Drug Product Fee</td>
<td>$15,486</td>
</tr>
<tr>
<td>100 Percent Generic New Animal Drug Sponsor Fee</td>
<td>$150,098</td>
</tr>
<tr>
<td>75 Percent Generic New Animal Drug Sponsor Fee</td>
<td>$112,574</td>
</tr>
<tr>
<td>50 Percent Generic New Animal Drug Sponsor Fee</td>
<td>$75,049</td>
</tr>
</tbody>
</table>

1 An animal drug sponsor is subject to only one fee each fiscal year.

VII. Fee Waiver or Reduction; Exemption From Fees

The types of fee waivers and reductions that applied last fiscal year still exist for FY 2019. However, a new exemption from fees was established by AGDUFA III, as follows:

Fees will not apply to any person who not later than September 30, 2023, submits to CVM a supplemental abbreviated application relating to a generic new animal drug approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3) of the FD&C Act (21 U.S.C. 352(w)(3)), if that person otherwise would be subject to user fees under AGDUFA based on the submission of the supplemental abbreviated application (21 U.S.C. 379–21(d)(2)).

VIII. Procedures for Paying FY 2019 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2019 fee schedule must be paid for an abbreviated new animal drug application subject to fees under AGDUFA III that is submitted on or after October 1, 2018. The payment must be made in U.S. currency from a U.S. bank
by one of the following methods: Wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at https://userfees.fda.gov/pay or the Pay.gov. payment option is available to you after you submit a cover sheet. (Note: only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select “Pay Now” to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please write your application’s unique Payment Identification Number, beginning with the letters “AG”, on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10005, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Conventry Lane, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA’s CVM. FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the Payment Identification Number described previously.

The tax identification number of FDA is 53–0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA website at https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm and scroll down the page until you find the link “Create AGDUFA User Fee Cover Sheet.” Select that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three—Send the payment for your application as described in section VIII.A.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2018, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2019 using this fee schedule. Fees will be due by January 31, 2019. FDA will issue invoices in November 2019 for any products and sponsors subject to fees for FY 2019 that qualify for fees after the December 2018 billing.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–20912 Filed 9–25–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA’s role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our website at: http://www.hrsa.gov/vaccinecompensation/index.html.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 et seq., provides that those seeking
compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that “[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the Federal Register.” Set forth below is a list of petitions received by HRSA on August 1, 2018, through August 31, 2018. This list provides the name of the petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading FOR FURTHER INFORMATION CONTACT), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, MD 20857. The Court’s caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.


George Siquoumas,
Administrator.

List of Petitions Filed

1. Dustin Bradley, San Diego, California, Court of Federal Claims No: 18–1123V
2. Richard Bishop, La Crosse, Wisconsin, Court of Federal Claims No: 18–1126V
3. Jocelyn Banda on behalf of A. B., El Centro, California, Court of Federal Claims No: 18–1127V
4. Dorothy J. Kapp, Louisville, Kentucky, Court of Federal Claims No: 18–1128V
5. Angela Beasley, Birmingham, Alabama, Court of Federal Claims No: 18–1130V
6. Terry Thornton, Huntsville, Alabama, Court of Federal Claims No: 18–1131V
7. Violet J. Barino, Florence, South Carolina, Court of Federal Claims No: 18–1132V
9. Yarah Alicea and Nicholas Kontos on behalf of V. K., Cutler Bay, Florida, Court of Federal Claims No: 18–1136V
10. Rabia Malik, Franklin, Ohio, Court of Federal Claims No: 18–1138V
11. Iris J. Jackson, Snellville, Georgia, Court of Federal Claims No: 18–1143V
12. Kathryn Nelson, Stillwater, Minnesota, Court of Federal Claims No: 18–1144V
14. Stacie Wilson, Hiawatha, Kansas, Court of Federal Claims No: 18–1148V
15. Gretchen Handy, Grand Forks, North Dakota, Court of Federal Claims No: 18–1149V
17. Robert Jamison, Harrison, Michigan, Court of Federal Claims No: 18–1152V
18. Evelyn Mazmanian, Cambridge, Massachusetts, Court of Federal Claims No: 18–1153V
19. Derek Roberts on behalf of Willie Roberts, Jr., Deceased, Seattle, Washington, Court of Federal Claims No: 18–1156V
20. Yovanny Alonzo, Bronx, New York, Court of Federal Claims No: 18–1157V
22. Beverly Ford, Temple, Texas, Court of Federal Claims No: 18–1160V
23. Heather Doucette, Ocala, Florida, Court of Federal Claims No: 18–1161V
25. Wayne F. Grant, Lakeland, Florida, Court of Federal Claims No: 18–1163V
26. Bonni Jean Arnold, Poway, California, Court of Federal Claims No: 18–1164V
27. Ashley Barkocy on behalf of M. B., Destin, Florida, Court of Federal Claims No: 18–1175V
29. Rosa M. Rios Morales and Juan Enrique Lozada Virella on behalf of I. K. L. R., Barranquitas, Puerto Rico, Court of Federal Claims No: 18–1190V
31. Kathryn E. McCready, Amherst, New York, Court of Federal Claims No: 18–1194V
32. Tara Brooks, Prescott Valley, Arizona, Court of Federal Claims No: 18–1195V
33. Patrick L. MaglioZZi, Carmel, Indiana, Court of Federal Claims No: 18–1196V
34. Susan Mogavero, San Diego, California, Court of Federal Claims No: 18–1197V
35. Robert Wharton and Debra Wharton on behalf of B. W., Boston, Massachusetts, Court of Federal Claims No: 18–1198V
36. Lucy Moore, Clifton, New York, Court of Federal Claims No: 18–1199V
37. Abeje Schnake, Glendale, Wisconsin, Court of Federal Claims No: 18–1201V
38. Shannon Delehanty, Conover, North Carolina, Court of Federal Claims No: 18–1202V
39. Christina Mecklenburg on behalf of H.M., Laguna Niguel, California, Court of Federal Claims No: 18–1203V
40. Megan McDonald on behalf of Malayna Grace McDonald, Patchogue, New York, Court of Federal Claims No: 18–1204V
41. Palestine McGowan, Tyler, Texas, Court of Federal Claims No: 18–1205V
42. Franline Lucinda Destin, North Miami, Florida, Court of Federal Claims No: 18–1206V
43. Lindsey Hettish, Coraopolis, Pennsylvania, Court of Federal Claims No: 18–1207V
44. Nancy Rissler, Frisco, Texas, Court of Federal Claims No: 18–1208V
45. Christina Christopher, White Oak, Pennsylvania, Court of Federal Claims No: 18–1209V
46. Garrett D. Polowy, Fairfax, Virginia, Court of Federal Claims No: 18–1210V
47. Dalvinder Singh Bains and Gurpal Kaur Bains on behalf of K.S.B., Yuba City, California, Court of Federal Claims No: 18–1212V
48. Leonard Thompson, Midland, Michigan, Court of Federal Claims No: 18–1217V
49. Barbara King Van Osdo, Indianapolis, Indiana, Court of Federal Claims No: 18–1219V
50. Thomas Schuster, Rogers, Minnesota, Court of Federal Claims No: 18–1220V
51. William O. Ledbetter, Piedmont, Alabama, Court of Federal Claims No: 18–1222V
52. Jean Golden, Clayton, New York, Court of Federal Claims No: 18–1223V
53. Mary McNally, Dresher, Pennsylvania, Court of Federal Claims No: 18–1228V
54. Donald Rink, Seattle, Washington, Court of Federal Claims No: 18–1231V
56. Leslie Nan Moon, North Bend, Washington, Court of Federal Claims No: 18–1233V
57. Ryan Hodges on behalf of S.H., Knotts Island, North Carolina, Court of Federal Claims No: 18–1234V
58. Kurt Sonnenburg, Madison, Wisconsin, Court of Federal Claims No: 18–1235V
59. Victoria Kantor, Naperville, Illinois, Court of Federal Claims No: 18–1236V
60. Jean Stone, Riverdale, New Jersey, Court of Federal Claims No: 18–1237V
61. Laurie Barreiro, Greensboro, North Carolina, Court of Federal Claims No: 18–1238V
62. Teresa Ortiz, Stockton, California, Court of Federal Claims No: 18–1239V
63. Elizabeth Salazar on behalf of D.R., Houston, Texas, Court of Federal Claims No: 18–1242V
64. Basil McNeely, Mobile, Alabama, Court of Federal Claims No: 18–1243V
66. Kayla Neuenschwander, Liberty Hill, Texas, Court of Federal Claims No: 18–1245V
68. Robert J. Lang, Palmdale, California, Court of Federal Claims No: 18–1247V
69. Cynthia L. Kiegiel, Newburgh, Indiana, Court of Federal Claims No: 18–1249V
70. Carey Shimada, Layton, Utah, Court of Federal Claims No: 18–1250V
71. Brooke Cloyd and Dylan Cloyd on behalf of B.T.C., Dallas, Texas, Court of Federal Claims No: 18–1251V
73. Norma Keller on behalf of Elizabeth Keller, Greensboro, North Carolina, Court of Federal Claims No: 18–1256V
74. Ashley Muller, Phoenix, Arizona, Court of Federal Claims No: 18–1258V
75. Tennie Komar, Boston, Massachusetts, Court of Federal Claims No: 18–1259V
76. Gerard Pepeta, Boston, Massachusetts, Court of Federal Claims No: 18–1262V
77. Donna Stearns, Washington, District of Columbia, Court of Federal Claims No: 18–1264V
78. William Dorris, Washington, District of Columbia, Court of Federal Claims No: 18–1265V
79. Tina Furlano, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–1266V
80. Ryan Bronson, Tampa, Florida, Court of Federal Claims No: 18–1267V
81. Lori A. Hildebrand, Pittsburgh, Pennsylvania, Court of Federal Claims No: 18–1268V
82. Richard Weastley, Burlington, North Carolina, Court of Federal Claims No: 18–1269V
83. Gloria Kirkpatrick, Cleveland, Tennessee, Court of Federal Claims No: 18–1271V
84. Sherrie Sandoval on behalf of Robert Sandoval, Deceased, Los Alamos, New Mexico, Court of Federal Claims No: 18–1272V
85. Latoria Martin, King of Prussia, Pennsylvania, Court of Federal Claims No: 18–1276V
86. Dianah Hernandez, Mineola, New York, Court of Federal Claims No: 18–1277V
87. Brian Gribbin, Peoria, Arizona, Court of Federal Claims No: 18–1278V
88. Shabnam Kouchak, Detroit, Michigan, Court of Federal Claims No: 18–1279V
89. Monica Hill, Dickinson, North Dakota, Court of Federal Claims No: 18–1282V
90. Melissa Papineau, Wichita, Kansas, Court of Federal Claims No: 18–1283V
91. Dolores A. Gorczyca, Memphis, Tennessee, Court of Federal Claims No: 18–1284V
93. Cynthia Pryor and Freddie Pryor, Jr. on behalf of L.P., Phoenix, Arizona, Court of Federal Claims No: 18–1288V
95. Terri L. Vanderjack, Westmont, Illinois, Court of Federal Claims No: 18–1292V
96. Donald Wolls, Blue Ash, Ohio, Court of Federal Claims No: 18–1294V
97. Lisa Oxera, Skillman, New Jersey, Court of Federal Claims No: 18–1295V
98. Craig Johnson, Bayport, Minnesota, Court of Federal Claims No: 18–1296V
100. Franklin Gallo, Washington, District of Columbia, Court of Federal Claims No: 18–1298V
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Next Generation Clinical Researchers in AD/ADRD.

Date: October 29, 2018.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact Person: Isis S. Mikhail, MD, MPH, MIKHAIL@MAIL.NIH.GOV.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)


Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–20841 Filed 9–25–18; 8:45 am]

BILLING CODE 4140–01–P
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting:

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Panel; Review of INBRE Applications.

Date: October 23, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at Chevy Chase Pavilion, 4300 Military Rd. NW, Washington, DC 20015.

Contact Person: Saraswathy Seetharam, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–2763, seetharams@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)


Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

FR Doc. 2018–20840 Filed 9–25–18; 8:45 am

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Mental Health Client/ Participant Outcome Measures

(OMB No. 0930–0285)—Revision

SAMHSA is requesting approval to add 13 questions to its existing Adult Measure data collection tool, and seven questions to its Child/Caregiver Measure data collection tool, for Center for Mental Health Services (CMHS) grantees. These additional questions are related to specific outcomes for specific grant programs. Grantees will be required to answer no more than four of the new questions, in addition to the existing questions on the data collection instruments. Currently, the information collected from this instrument is entered and stored on SAMHSA’s Performance Accountability and Reporting System, which is a real-time, performance management system that captures information on the substance abuse treatment and mental health services delivered in the United States. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 (GPRMA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs, which are consistent with OMB guidance.

SAMHSA and its Centers will use the data collected for annual reporting required by GPRMA, to describe and understand changes in outcomes from baseline to follow-up to discharge. SAMHSA’s report for each fiscal year will include actual results of performance monitoring for the three preceding fiscal years. Information collected through this request will allow SAMHSA to report on the results of these performance outcomes as well as be consistent with SAMHSA-specific performance domains, and to assess the accountability and performance of its discretionary grant programs. The additional information collected through this request will allow SAMHSA to improve its ability to assess the impact of its programs on key outcomes of interest and to gather vital diagnostic information about clients served by CMHS discretionary grant programs.

Changes have been made to add a total of 13 questions to the existing Adult tool, and seven questions to the Child/Caregiver tool. Questions will be selected by SAMHSA based on the specific goals and characteristics of the grant program. The 13 questions added to the Adult tool are:

(1) Behavioral Health Diagnoses—Please indicate patient’s current behavioral health diagnoses using the International Classification of Diseases, 10th revision, Clinical Modification (ICD–10–CM) codes listed below.

(2) [For client] In the past 30 days, how often have you taken all of your psychiatric medication(s) as prescribed to you?

(3) [For grantee] In the past 30 days, how compliant has the client been with their treatment?

(4) [For grantee] Did the client screen positive for a mental health or co-occurring disorder?

a. Mental health disorder.
b. Co-occurring disorder.

(i) If client screened positive, was the client referred to the following types of services?

(1) Mental health services.

(2) Co-occurring services.

(ii) If client was referred to services, did they receive the following services?

(1) Mental health services.

(2) Co-occurring services.

(5) [For client] Please indicate the degree to which you agree or disagree with the following statement: Receiving community-based services through the [insert grantee name] program has helped me to avoid further contact with the police and the criminal justice system.

(6) [For client] In the past 30 days, how many times have you:

(i) Been to the emergency room for a physical health care problem?

(ii) Been hospitalized for a physical health care problem?

(7) [For grantee] Please indicate which type of funding source(s) that was (were) used to pay for the services provided to this client since their last interview. (Check all that apply):

(a) Current SAMHSA grant funding.

(b) Other federal grant funding.

(c) State funding.

(d) Client’s private insurance.

(e) Medicaid/Medicare.

(f) Other [Specify]:

(8) [For client] Did the program provide the following:
(a) HIV test?
   (i) If yes, what was the result?
   (ii) If result was positive, were you connected to treatment services?
(b) Hepatitis B (HBV) test?
   (i) If yes, what was the result?
   (ii) If result was positive, were you connected to treatment services?
(c) Hepatitis C (HCV) test?
   (i) If yes, what was the result?
   (ii) If result was positive, were you connected to treatment services?
(d) Did you receive a referral from [grantee] to medical care?
(e) Have you been prescribed an antiretroviral medication (ART)?
   (i) For clients who report being prescribed an ART: In the past 30 days, how often have you taken your ART as prescribed?
   (ii) Have you been prescribed an ART: In the past 30 days, how often have you taken your ART as prescribed?
(f) Did you receive a referral from [grantee] to medical care?
(g) Have you been prescribed an antiretroviral medication (ART)?
   (i) For clients who report being prescribed an ART: In the past 30 days, how often have you taken your ART as prescribed?
   (ii) Have you been prescribed an ART: In the past 30 days, how often have you taken your ART as prescribed?
(h) Did you receive a referral from [grantee] to medical care?
(i) Have you been prescribed an antiretroviral medication (ART)?
   (i) For clients who report being prescribed an ART: In the past 30 days, how often have you taken your ART as prescribed?
   (ii) Have you been prescribed an ART: In the past 30 days, how often have you taken your ART as prescribed?
(j) Did you receive a referral from [grantee] to medical care?
(k) Have you been prescribed an antiretroviral medication (ART)?
   (i) For clients who report being prescribed an ART: In the past 30 days, how often have you taken your ART as prescribed?
   (ii) Have you been prescribed an ART: In the past 30 days, how often have you taken your ART as prescribed?

Written comments and recommendations concerning the proposed information collection should be sent by October 26, 2018 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB’s receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov. Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503.
DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2018–0029]

Privacy Act of 1974; System of Records

AGENCY: Department of Homeland Security.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to modify a current DHS system of records titled, “DHS/All-016 Correspondence Records System of Records.” This system of records allows the Department to collect and maintain correspondence records. The Department is updating this system of records to reflect changes to the categories of individuals, categories of records, and routine uses. Specifically, these changes include expanding the categories of individuals to include third party subjects of correspondence who may not be the sender or recipient. The Department is also expanding the categories of records to permit the collection of an individual’s phone number, call and customer service center records, receipt number, case numbers relevant to the correspondence, and account IDs associated with correspondence between the Department and the responding party. DHS is updating routine use (E) and adding routine use (F) to comply with new policies pertaining to data breach procedures. The Department is making non-substantive edits to the routine uses to align with previously published Department systems of records notices (SORNs). Lastly, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice. This modified system will be included in the DHS inventory of record systems.

DATES: Submit comments on or before October 26, 2018. This modified system will be effective upon publication. New or modified routine uses will become effective October 26, 2018.

ADDRESSES: You may submit comments, identified by docket number DHS–2018–0029 by one of the following methods:
  - Fax: 202–343–4010.

Instructions: All submissions received must include the agency name and docket number DHS–2017–0029. All comments received will be posted without change to http://www.regulations.gov, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: For general and privacy questions, please contact: Philip S. Kaplan, Privacy@hq.dhs.gov, 202–343–1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

SUPPLEMENTARY INFORMATION:

I. Background

DHS is updating this Department-wide SORN under the Privacy Act for DHS correspondence records. DHS will use this system to collect and maintain correspondence records submitted by the general public, DHS personnel, and others. This SORN does not apply to correspondence related to Freedom of Information Act (FOIA) or Privacy Act requests, or to correspondence received in the course of standard immigration benefit application processes. This SORN also does not cover the underlying records associated with a response to correspondence.

This system allows DHS to collect and maintain incoming information and responses to inquiries, comments, or complaints made to the Department. Categories of individuals, categories of records, and routine uses of this system of records notice have been updated to better reflect the Department’s correspondence record systems. This system modification will expand the categories of individuals to cover third parties whose information is submitted by the sender or recipient through an inquiry, comment, or complaint. DHS may collect and respond to this information from a third party. However, any investigations or awards initiated as a consequence of a third party’s correspondence would not be covered under this SORN. DHS is also expanding the categories of records to permit the collection of an individual’s phone number, call and customer service center records, receipt number, and case or account number associated or referenced in the correspondence. DHS is modifying routine use (E) and adding routine use (F) to conform to Office of Management and Budget (OMB) Memorandum M–17–12, “Preparing for and Responding to a Breach of Personally Identifiable Information” (Jan. 3, 2017). All following routine uses are being re-lettered to account for the additional routine use. Non-substantive language changes have been made to additional routine uses to clarify disclosure policies that are standard across DHS and to align with previously published DHS SORNs. This modified system will be included in DHS’s inventory of record systems.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which Federal Government agencies collect, maintain, use, and disseminate individuals’ records. The Privacy Act applies to information that is maintained in a “system of records.” A “system of records” is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. Additionally, the Judicial Redress Act (JRA) provides a statutory right to covered persons to make requests for access and amendment to covered records, as defined by the JRA, along with judicial review for denials of such requests. In addition, the JRA prohibits disclosures of covered records, except as otherwise permitted by the Privacy Act.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to OMB and to Congress.

SYSTEM NAME AND NUMBER:

SECURITY CLASSIFICATION:
Unclassified.

SYSTEM LOCATION:
Records are maintained at several Headquarters locations and in component offices of the Department of Homeland Security, in both Washington, DC and field locations.
SYSTEM MANAGER(S):
For DHS Headquarters, the System Manager is the Chief Information Officer, cio@hq.dhs.gov, 202–447–3735, Department of Homeland Security, Washington, DC 20528. For components of DHS, the System Managers are their respective Chief Information Officers. Links to component contact information can be found at https://www.dhs.gov/direct-contact-information under “Contact information for DHS Components.”

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

PURPOSE(S) OF THE SYSTEM:
The purpose of this system is to manage all correspondence including incoming information and responses to inquiries, comments, or complaints made to DHS.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:
Individuals who submit inquiries, complaints, comments, or other correspondence to DHS, excluding Privacy Act or FOIA requests, or standard immigration applications; individuals who are the subject of the correspondence; and any responding individual on behalf of DHS are covered by this SORN.

CATEGORIES OF RECORDS IN THE SYSTEM:
- Full name;
- Physical and mailing addresses;
- Email address;
- Phone number;
- Web form information (e.g., IP addresses);
- Who the complaint, compliment, comment, or issue is about;
- Incoming correspondence excluding Privacy Act or FOIA requests, or standard immigration applications;
- DHS’s reply;
- Responders name on behalf of DHS;
- Call and Customer Service Center records (to include recordings of calls and online real time interactions with customer service representatives);
- Associated case or file numbers (e.g., Alien Number);
- Receipt number;
- Account ID;
- Additional unsolicited personal information provided by the individual (including Social Security number); and
- Other related materials.

RECORD SOURCE CATEGORIES:
Records are obtained from all sources of incoming correspondence and responses by DHS. A non-exclusive list of correspondence sources includes members of the general public, call and customer service centers, unions, trade organizations, non-profits, business or governmental entities, including the news media and congressional offices.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:
In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:
A. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys, or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:
1. DHS or any component thereof;
2. Any employee or former employee of DHS in his/her official capacity;
3. Any employee or former employee of DHS in his/her individual capacity when DOJ or DHS has agreed to represent the employee; or
4. The United States or any agency thereof.
B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.
C. To the National Archives and Records Administration or General Services Administration pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.
D. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.
E. To appropriate agencies, entities, and persons when (1) DHS suspects or has confirmed that there has been a breach of the system of records; (2) DHS has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DHS (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS’s efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.
F. To another Federal agency or Federal entity, when DHS determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.
G. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.
H. To an appropriate Federal, state, tribal, territorial, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, when a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.
I. To another Federal agency to refer correspondence or respond to correspondence given the nature of the complaint, compliment, comment, or issue.
J. To unions recognized as exclusive bargaining representatives of the individual under the Civil Service Reform Act of 1978, 5 U.S.C. 7111 and 7114, the Merit Systems Protection Board, arbitrators, the Federal Labor Relations Authority, and other parties responsible for the administration of the Federal labor-management program for the purpose of processing any corrective action, or grievances, or conducting administrative hearings or appeals, or if needed in the performance of other authorized duties.
K. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information, when disclosure is necessary to preserve confidence in the integrity of DHS, or when disclosure is necessary to demonstrate the
accountability of DHS’s officers, employees, or individuals covered by the system, except to the extent the Chief Privacy Officer determines that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

DHS stores records in this system electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by individual name and date of correspondence.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Executive level records are permanent and files are cut off annually and transferred to the National Archives and Records Administration 15 years after cut-off date, in accordance with National Archives and Records Administration (NARA) General Schedule DAA–0563–2013–0005–0003. Public correspondence and communication that require no formal response or action are temporary and are destroyed when 90 days old, unless longer retention is authorized when required for business use, in accordance with NARA General Records Schedule (GRS) 6.4, item 20. Correspondence relating to a specific case or action is not considered public correspondence and will be filed and maintained with the appropriate case or action file under its specific retention schedule. DHS Components may create their own retention schedules for correspondence received. NARA GRS 4.1, item 010, covers when a Department, Component, office, or individual is tasked to review the correspondence or inquiry. Actual assignments and any reminder emails that an action is required are destroyed immediately, or when no longer needed for reference.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DHS safeguards records in this system according to applicable rules and policies, including all applicable DHS automated systems security and access policies. DHS has imposed strict controls to minimize the risk of compromising the information that is being stored. Access to any paper files or computer systems containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

Individuals seeking access to and notification of any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Chief Privacy Officer and Chief FOIA Officer, or a component FOIA Officer, whose contact information can be found at http://www.dhs.gov/foia under “contact information.” If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief Freedom of Information Act Officer, Department of Homeland Security, Washington, DC 20528–0655. Even if neither the Privacy Act nor the JRA provide a right of access, certain records about a person may be available under FOIA.

When an individual is seeking records about himself or herself from this system of records or any other Departmental system of records, the individual’s request must conform with the Privacy Act regulations set forth in 6 CFR part 5. The individual must first verify his/her identity, meaning that the individual must provide his/her full name, current address, and date and place of birth. The individual must sign the request, and the individual’s signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, an individual may obtain forms for this purpose from the Chief Privacy Officer and Chief Freedom of Information Act Officer, http://www.dhs.gov/foia or 1–866–431–0486. In addition, the individual should:

• Examine why the individual believes the Department would have information on him/her;
• Identify which component(s) of the Department the individual believes may have the information about him/her;
• Specify when the individual believes the records would have been created; and
• Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If an individual’s request is seeking records pertaining to another living individual, the first individual must include, in accordance with 6 CFR part 5.21, a statement from the second individual certifying his/her agreement for the first individual to access his/her records. Without the above information, the component(s) may not be able to conduct an effective search, and the individual’s request may be denied due to lack of specificity or lack of compliance with applicable regulations.

CONTESTING RECORD PROCEDURES:

For records covered by the Privacy Act or covered JRA records, see “Record Access Procedures” above, and 6 CFR part 5.

NOTIFICATION PROCEDURES:

See “Record Access Procedures.”

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

73 FR 66657.

Philip S. Kaplan,
Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2018–20876 Filed 9–25–18; 8:45 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6081–D–02]

Redelegation of Authority for the Office of Field Policy and Management

AGENCY: Office of Field Policy and Management, HUD.

ACTION: Notice of Redelegation of Authority.

SUMMARY: Through this notice, the Assistant Deputy Secretary for Field Policy and Management and the Associate Assistant Deputy Secretary for Field Policy and Management redelegates certain operational management authority to the HUD regional administrators located in Region I (Boston, MA); Region II (New York, NY); Region III (Philadelphia, PA); Region IV (Atlanta, GA); Region V (Chicago, IL); Region VI (Fort Worth, TX); Region VII (Kansas City, KS); Region VIII (Denver, CO); Region IX (San Francisco, CA); and Region X (Seattle, WA).

DATES: Applicable Date: September 19, 2018.

FOR FURTHER INFORMATION CONTACT: John B. Shumway, Assistant General Counsel, Administrative Law Division, Department of Housing and Urban Development at 451 7th Street SW, Room 9262; Washington, DC 20410–0500 or at telephone number, 202–402–3502 (this is not a toll-free number). This number may be accessed through TTY by calling the Federal Relay Service, toll-free, at 800–877–8339.
SUPPLEMENTARY INFORMATION: By separate notice published in today’s Federal Register, the Secretary of HUD delegates to the Assistant Deputy Secretary for Field Policy and Management and the Associate Assistant Deputy Secretary for Field Policy and Management authority for the management and oversight of the Department’s field operations, and further authorizes the Assistant Deputy Secretary and Associate Assistant Deputy Secretary to delegate such authority. Through this notice, the Assistant Deputy Secretary for Field Policy and Management and the Associate Assistant Deputy Secretary for Field Policy and Management delegate certain operational management authority to the HUD regional administrators. This notice supersedes these and all prior delegations to the HUD regional administrators.

Section I: Authority Redelegated

A. Cross-Program Coordination. Each regional administrator is redelegated the following duties:
1. Develop and implement place-based Regional and Field Operating Plans in consultation with field program directors.
2. To develop, approve, track, and oversee the Regional Operating Plan priority projects and initiatives that cross program office lines.
3. Prepare briefing papers and hot issue reports.
4. Lead disaster relief efforts.
5. Convene on-site program teams (e.g., Community Planning and Development, Office of General Counsel, Fair Housing and Equal Opportunity, Public and Indian Housing, etc.), as necessary and in consultation with field program directors, to review proposed, major projects or initiatives for place-based impact.
6. Assist state and local housing officials in assessing the impact of housing foreclosures.
7. Convene place-based teams, as necessary and in consultation with field program directors, to review Consolidated Plans during the 45-day review period.
8. Provide comments to Public and Indian Housing field directors on public housing disposal and/or demolition applications.
9. Review with other program leaders the status of the HUD–VASH program to maximize utilization.
10. Consult with program directors regarding implementation of departmental goals, secretarial and presidential initiatives, and Annual Performance Plan commitments. Regional administrators can request review by Headquarters of decisions made by program directors. Where the regional administrator and relevant program director disagree on a major program decision, the regional administrator may report the disagreement to the Assistant Deputy Secretary for Field Policy and Management, who may then raise the matter with the relevant Assistant Secretary or equivalent. The relevant Assistant Secretary or equivalent makes the final determination, subject to review by the Deputy Secretary, as necessary.

B. Administrative Management. Each regional administrator is delegated the following administrative duties:
1. Manage administrative field operation, applicable to all employees at a duty location, including outstationed personnel, through coordination with program directors administrative offices, and supervisors of outstationed personnel. Administrative field operations include, but are not limited to:
   • Determining official local office hours of operation.
   • Determining emergency office closings due to weather, disaster, or local events.
   • Providing effective customer service.
   • Working with program directors and all employees to foster a positive working environment.
   • Coordinating with the Office of Administration (and its Office of Administrative Region Support Manager) to develop and manage an administrative budget that meets the needs of programs and staff in each office.
   • Managing internal office communications of a general nature.
2. Regional administrators may request a waiver of specific directives and handbook provisions pertaining to programs in the offices of Housing, Public and Indian Housing, Community Planning and Development, and Fair Housing and Equal Opportunity. Waiver is not authorized for the HUD Litigation Handbook and regulations, or those departmental directives and handbook provisions mandated by or directly predicated on a statute, Executive order, or regulation. Waiver requests by the regional administrator will be forwarded to the Assistant Deputy Secretary for Field Policy and Management, who will forward the requests to the respective program Assistant Secretary for final decision. All waiver requests must be in writing and specify the grounds for requesting the waiver. Regional administrators will be notified in writing of the program Assistant Secretary’s decision, through the Office of Field Policy and Management leadership. Only the program Assistant Secretary, or other program office officials with delegated authority to do so, may grant waivers or make a specific delegation of waiver authority.

C. Representation. Each regional administrator is redelegated the following duties:
1. Oversee labor/management relations in the region in coordination with the assigned Employee and Labor Relations representative.
2. Work with Headquarters offices, including the Office of Congressional and Intergovernmental Relations, to ensure that Federal, state, local and tribal elected officials within a jurisdiction receive responsive and coordinated customer service. This in no way supersedes the Secretary’s delegation of authority to the Assistant Secretary for Congressional and Intergovernmental Relations on October 7, 2011 (Federal Register Docket No. FR–5515–D–01), in which the Secretary delegates to the Assistant Secretary for Congressional and Intergovernmental Relations authority and responsibility for coordinating congressional and intergovernmental relations activities.
3. Manage all field-controlled congressional and intergovernmental correspondence, in consultation with field program directors and in coordination with the Executive Secretariat (Office of Administration) and the Office of Congressional and Intergovernmental Relations.
4. Respond to all media inquiries in conjunction with Headquarters’ Office of Public Affairs and field program directors.
5. Administer the local office’s web page and internet sources, in coordination with the Office of Public Affairs.
6. Monitor and evaluate customer service.
7. Enter into cosponsorship agreements, with the concurrence of the General Counsel and the relevant program Assistant Secretary or equivalent.
Section II: Authority To Redelegate

Except for those authorities specifically excluded in Section III of this notice, this authority may be redelegated, as appropriate, from regional administrators to field Office directors within the respective jurisdictions.

Section III: Authority Nonredelegable

The following authorities may not be redelegated from the regional administrators to the field office directors or to any other employee:
1. The authority to enter into co-sponsorship agreements.
2. The authority to request waivers as provided by section I.B.3. above.
3. The authority to sign local, area-wide, or center-wide negotiated impact and implementation or memorandum of understanding agreements with unions representing smaller units consisting of either Headquarters and/or field employees on issues confined to a single program area and within the regional administrators' own budget authority, including the resolution of unfair labor practice charges and bargaining impasses.

Section IV: Delegations Superseded

This notice supersedes all prior delegations of authority to the regional directors/administrators from the Secretary of HUD or the Assistant Deputy Secretary for Field Policy and Management.

Authority: Section 7(d)(q) of the Department of HUD Act, 42 U.S.C. 3535(d).
Matthew F. Hunter,
Assistant Deputy Secretary for Field Policy and Management.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[DOcket No. FR–6081–D–01]

Delegation of Authority for the Office of Field Policy and Management

AGENCY: Office of the Secretary, HUD.
ACTION: Notice of delegation of authority.

SUMMARY: Through this notice, the Secretary of the Department of Housing and Urban Development delegates to the Assistant Deputy Secretary for Field Policy and Management and to the Associate Assistant Deputy Secretary for Field Policy and Management authority for the management and oversight of the Department’s field operations.

DATES: Applicable Date: September 19, 2018.

FOR FURTHER INFORMATION CONTACT: John B. Shumway, Assistant General Counsel, Administrative Law Division, Department of Housing and Urban Development, at 451 7th Street SW, Room 9262; Washington, DC 20410–0500 or telephone number 202–402–5190 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the Federal Relay Service, toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Previous delegations of authority from the Secretary of HUD to the Assistant Deputy Secretary for Field Policy and Management are hereby revoked and superseded, including the delegations published on October 19, 2012 (77 FR 64394).

Section A. Authority

1. Field Operations. The Secretary of HUD hereby delegates to the Assistant Deputy Secretary for Field Policy and Management and the Associate Assistant Deputy Secretary for Field Policy and Management authority for the management and oversight of the Department’s field operations. In carrying out this authority, the Assistant Deputy Secretary for Field Policy and Management and the Associate Assistant Deputy Secretary for Field Policy and Management shall, among other duties:
   a. Coordinate the implementation of the Department’s policies and programs in the field in consultation with field program directors. Program coordination does not mean program decision-making but, rather, collecting local information, measuring community impact, initiating cross-program communication and coordination, and facilitating the resolution of potential program differences through the appropriate channels, if necessary.
   b. Manage and assess field resources to ensure that operations are efficient and effective.
   c. Coordinate and convey the Strategic Plan and Regional or Local Operating Plans with the field.
   d. Advise the Secretary on policy and management of the field.
   e. Consult with program directors regarding implementation of departmental management goals, secretarial and presidential initiatives, and Annual Performance Plan commitments.
2. Promise Zone Initiative. The Secretary delegates to the Assistant Deputy Secretary for Field Policy and Management and the Associate Deputy Secretary for Field Policy and Management all power and authority for the day-to-day operations and administrative functions related to the Promise Zone Initiative. The Promise Zone Initiative supports the Department’s responsibilities under sections 2 and 3 of the HUD Act, 42 U.S.C. 3531–32, to assist the President in achieving maximum coordination of the various Federal activities that have a major effect upon urban community, suburban, or metropolitan development; to develop and recommend to the President policies for fostering orderly growth and development of the Nation’s urban areas; and to exercise leadership, at the direction of the President, in coordinating Federal activities affecting housing and urban development. This authority includes coordination of the selection process and the development of resulting recommendations.
   The delegated authority related to the Promise Zone Initiative does not include the authority to issue or waive Notices of Funding Availability or the equivalent, regulations, or statutes, but does include the authority to redelegate the authority provided.

3. Davis-Bacon and Labor Standards. The Secretary delegates to the Assistant Deputy Secretary for Field Policy and Management and the Associate Deputy Secretary for Field Policy and Management all authority with respect to Davis-Bacon and Labor Standards administration and enforcement vested in, or delegated or assigned to, the Secretary under statutes and other authorities relating to Davis-Bacon and Labor Standards, including, but not limited to, the Davis-Bacon Act (40 U.S.C. 3141 et seq.), the Copeland Act (40 U.S.C. 3145), the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 et seq.), Reorganization Plan No. 14 of 1950 (5 U.S.C. App. 1 Reorg. Plan 14), the National Housing Act (12 U.S.C. 1701 et seq.), Section 202 of the National Housing Act of 1959 (12 U.S.C. 1701q), the National Affordable Housing Act (42 U.S.C. 12704 et seq.), the United States Housing Act of 1937 (42 U.S.C. 1437), the Housing and Community Development Act of 1974 (42 U.S.C. 5301 et seq.), the Native American Housing Assistance and Self-Determination Act (25 U.S.C. 4101 et seq.), Executive Order 13502 (74 FR 6985), and certain Department of Labor regulations (29 CFR parts 1, 3, 5, 6, and 7).
   The authority delegated includes the authority to determine or adopt prevailing wage rates, which is vested in the Secretary by certain statutes,
including, but not limited to, the United States Housing Act of 1937 (42 U.S.C. 1437j) and the Native American Housing Assistance and Self-Determination Act (25 U.S.C. 4101 et seq.).

Section B. Authority To Redelegate

The Assistant Deputy Secretary for Field Policy and Management and the Associate Assistant Deputy Secretary for Field Policy and Management are authorized to redelegate to employees of HUD any of the authority delegated under section A above.

Section C. Authority Superseded

This Delegation supersedes all previous delegations from the Secretary of HUD to the Assistant Deputy Secretary for Field Policy and Management.

Authority: Section 7(d), Department of Housing and Urban Development Act (42 U.S.C. 5335(d)).

Benjamin S. Carson Jr., Secretary.

[FR Doc. 2018–20963 Filed 9–25–18; 8:45 am]
BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[18X.LLAZ2910000.L14400000.BJ0000. LXXSA2250000.241A]

Notice of Public Meeting, North Slope Science Initiative—Science Technical Advisory Panel, Alaska

AGENCY: Bureau of Land Management, Alaska, Interior.

ACTION: Notice of public meeting.


DATES: The STAP will meet October 23 and 24, 2018, from 8:30 a.m. to 5 p.m. each day. There will be a public comment period from 3:30 p.m. until 4 p.m. on Tuesday, October 23.

DIRECTIONS: The meeting will be on the first floor of the Atwood Conference Center in the Ted Stevens Room, #102, at 550 West Seventh Avenue, Anchorage, Alaska.

FOR FURTHER INFORMATION CONTACT: Mr. Scott Guyer, Deputy Director (Acting), North Slope Science Initiative, Bureau of Land Management, 222 West Seventh Avenue, Mailstop 13, Anchorage, Alaska 99513, 907–271–3284, or sguyer@blm.gov. People who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

Authorized by Public Law 109–58, Sec. 348 (42 U.S.C. 15906) of the Energy Policy Act of 2005, the STAP provides advice and recommendations to the NSSI Oversight Group about priority information requirements for management decisions across the North Slope of Alaska. These priority information requirements and recommendations may include inventory, monitoring, and research activities that contribute to informed resource management decisions. The Secretary of the Interior appoints panel members who represent various scientific and technical disciplines.

This meeting will include background presentations to inform panel work; updates from panel working groups on topics including aviation impacts on subsistence resources, habitat monitoring, focal species monitoring, and indigenous knowledge; and development of a communications plan to facilitate NSSI actions for ensuring effective coordination of monitoring and research activities.

There will be a public comment period from 3:30 p.m. until 4:00 p.m. on Tuesday, October 23. Depending on the number of people wishing to comment within the scheduled time available, there may be limited time for individuals to speak. Individuals who plan to attend and need special assistance, such as sign language interpretation, transportation, or other reasonable accommodations, should contact the NSSI’s Deputy Director. The public may present written comments to the STAP through the NSSI’s Deputy Director. 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.


Karen E. Mouritsen, Acting State Director, Alaska.

[FR Doc. 2018–20938 Filed 9–25–18; 8:45 am]
BILLING CODE 4310–JA–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[18X.LLAZ9210000.L14400000.BJ0000. LXSSA2250000.241A]

Notice of Filing of Plats of Survey; Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of the following described lands were officially filed in the Bureau of Land Management (BLM), Arizona State Office, Phoenix, Arizona, on the dates indicated. Surveys announced in this notice are necessary for the management of lands administered by the agencies indicated.

ADDRESSES: These plats will be available for inspection in the Arizona State Office, Bureau of Land Management, One North Central Avenue, Suite 800, Phoenix, Arizona, 85004–4427. Protests of the survey should be sent to the Arizona State Director at the above address.

FOR FURTHER INFORMATION CONTACT: Gerald Davis, Chief Cadastral Surveyor of Arizona; (602) 417–9558; gtdavis@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

The Gila and Salt River Meridian, Arizona

The plat, in one sheet, representing the dependent resurvey and subdivision of sections 15, 16 and 22, Township 21 North, Range 1 East, accepted September 13, 2018, and officially filed September 17, 2018, for Group 1181, Arizona.

This plat was prepared at the request of the United States Forest Service. The plat, in one sheet, representing the subdivision of section 19, and a
metes-and-bounds survey in section 19, mostly surveyed Township 9 North, Range 3 East, accepted September 18, 2018, and officially filed September 20, 2018, for Group 1176, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The plat, in one sheet, representing the dependent resurvey and subdivision of section 4, Township 22 North, Range 1 West, accepted September 13, 2018, and officially filed September 17, 2018, for Group 1181, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The supplemental plat, in one sheet, showing the amended lotting in sections 13 and 14, Township 41 North, Range 7 West, accepted July 26, 2018, and officially filed July 30, 2018, for Group 9113, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The plat, in one sheet, representing the dependent resurvey, survey and metes-and-bounds surveys in certain sections, partially surveyed Township 3 North, Range 8 West, accepted September 13, 2018, and officially filed September 17, 2018, for Group 1160, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The plat, in three sheets, representing the dependent resurvey, subdivision of sections 22 and 33, Township 13 North, Range 4 West, accepted July 26, 2018, and officially filed July 30, 2018, for Group 1182, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The plat, in one sheet, representing the dependent resurvey and subdivision of sections 28 and 33, Township 13 North, Range 4 West, accepted September 13, 2018, and officially filed September 20, 2018, for Group 1182, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

The plat, in three sheets, representing the dependent resurvey, subdivision of sections 11 and 12, Township 3 North, Range 4 North, accepted July 26, 2018, and officially filed July 30, 2018, for Group 1174, Arizona.

This plat was prepared at the request of the Bureau of Land Management.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within 30 days after the protest is filed. Before including your address, or other personal information in your protest, please be aware that your entire protest, 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.

**Authority:** 43 U.S.C. Chap. 3.

**Gerald T. Davis,**
Chief Cadastral Surveyor of Arizona.

**FOR FURTHER INFORMATION CONTACT:**

Gerald T. Davis, Chief Cadastral Surveyor of Arizona.

[FR Doc. 2018–20945 Filed 9–25–18; 8:45 am]

**BILLING CODE 4310–32–P**

**INTERNATIONAL TRADE COMMISSION**

**[Investigation Nos. 731–TA–875, 878, 880, and 882 (Third Review)]**

**Steel Concrete Reinforcing Bar From Belarus, China, Indonesia, Latvia, Moldova, Poland, and Ukraine; Scheduling of Expedited Five-Year Reviews**

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice of the scheduling of expedited reviews pursuant to the Tariff Act of 1930 ("the Act") to determine whether revocation of the antidumping duty orders on steel concrete reinforcing bar from Belarus, China, Indonesia, Latvia, Moldova, Poland, and Ukraine would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

**DATES:** September 4, 2018.

**FOR FURTHER INFORMATION CONTACT:**


General information concerning the Commission may also be obtained by accessing its internet server (https://www.usitc.gov). The public record for this review may be viewed on the Commission’s electronic docket (EDIS) at https://edis.usitc.gov.

**SUPPLEMENTARY INFORMATION:**

**Background.**—On September 4, 2018, the Commission determined that the domestic interested party group response to its notice of institution (83 FR 25490, June 1, 2018) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate in each review. The Commission did not find any other circumstances that would warrant conducting full reviews. Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of these reviews and rules of general application, consult the Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

**Staff report.**—A staff report containing information concerning the subject matter of the reviews will be placed in the nonpublic record on October 3, 2018, and made available to persons on the Administrative Protective Order service list for these reviews. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission’s rules.

**Written submissions.**—As provided in section 207.62(d) of the Commission’s rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution, and any party other than an interested party to the reviews may file written comments with the Secretary on what determination the Commission should reach in the reviews. Comments are due on or before October 9, 2018, and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by October 9, 2018. However, should the...
Department of Commerce ("Commerce") extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce’s final results is three business days after the issuance of Commerce’s results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s rules with respect to filing were revised effective July 25, 2014. See 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission’s website at https://edis.usitc.gov.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

**Determination.**—The Commission has determined these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

**Authority:** These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission’s rules.

By order of the Commission.


Lisa Barton,
Secretary to the Commission.

[FR Doc. 2018–20925 Filed 9–25–18; 8:45 am]

**BILLING CODE 7020–02–P**

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**INTERNATIONAL TRADE COMMISSION**

**[Investigation Nos. 701–TA–610 and 731–TA–1425–1427 (Preliminary)]**

**Refillable Stainless Steel Kegs From China, Germany, and Mexico; Institution of Anti-Dumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations**

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–610 and 731–TA–1425–1427 (Preliminary) pursuant to the Tariff Act of 1930 ("the Act") to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of stainless steel kgs from China, Germany, and Mexico, provided for in subheadings 7310.10.00 and 7310.29.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Government of China. Unless the Department of Commerce ("Commerce") extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by November 5, 2018. The Commission’s views must be transmitted to Commerce within five business days thereafter, or by November 13, 2018.

**DATES:** September 20, 2018.


Hearing-impaired persons can obtain information on this matter 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 (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:**

**Background:**—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a) and 1677b(a)), in response to a petition filed on September 20, 2018, by American Keeg Company LLC, Pottstown, Pennsylvania.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

**Participation in the investigations and public service list.** Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission’s rules, not later than seven days after publication of this notice in the Federal Register. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

**Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.**—Pursuant to section 207.7(a) of the Commission’s rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the Federal Register. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

**Conference.**—The Commission’s Director of Investigations has scheduled a conference in connection with these investigations for 9:30 a.m. on Thursday, October 11, 2018, at the U.S. International Trade Commission Building, 500 E Street SW, Washington, DC. Requests to appear at the conference should be emailed to preliminaryconferences@usitc.gov (DO NOT FILE ON EDIS) on or before October 9, 2018. Parties in support of the imposition of countervailing and antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission’s deliberations may request permission to present a short statement at the conference.

**Written submissions.**—As provided in sections 201.8 and 207.15 of the Commission’s rules, any person may submit to the Commission on or before October 16, 2018, a written brief containing information and arguments pertinent to the subject matter of the
investigations. Parties may file written testimony in connection with their presentation at the conference. All written submissions must conform with the provisions of section 201.8 of the Commission’s rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s Handbook on E-Filing, available on the Commission’s website at https://edis.usitc.gov, elaborates upon the Commission’s rules with respect to electronic filing.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Certification.—Pursuant to section 207.3 of the Commission’s rules, any person submitting information to the Commission in connection with these investigations must certify that the information is accurate and complete to the best of the submitter’s knowledge. In making the certification, the submitter will acknowledge that any information that it submits to the Commission during these investigations may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of these or related investigations or reviews, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission’s rules.

By order of the Commission.


Lisa Barton,
Secretary to the Commission.

[FR Doc. 2018–20926 Filed 9–25–18; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1203 (Review)]

Xanthan Gum From China; Scheduling of an Expedited Five-Year Review


ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 (“the Act”) to determine whether revocation of the antidumping duty order on xanthan gum from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.


General information concerning the Commission may also be obtained by accessing its internet server (https://www.usitc.gov). The public record for this review may be viewed on the Commission’s electronic docket (EDIS) at https://edis.usitc.gov.

SUPPLEMENTARY INFORMATION:
Background.—On September 4, 2018, the Commission determined that the domestic interested party group response to its notice of institution (83 FR 25485, June 1, 2018) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review. Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of this review and rules of general application, consult the Commission’s Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207,

A record of the Commissioners’ votes, the Commission’s statement on adequacy, and any individual Commissioner’s statements will be available from the Office of the Secretary and at the Commission’s website.

subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the review will be placed in the nonpublic record on September 26, 2018, and available to persons on the Administrative Protective Order service list for this review. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission’s rules.

Written submissions.—As provided in section 207.62(d) of the Commission’s rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution, and any party other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before October 1, 2018 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by October 1, 2018. However, should the Department of Commerce (“Commerce”) extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce’s final results is three business days after the issuance of Commerce’s results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission’s rules. The Commission’s rules with respect to filing were revised effective July 25, 2014. See 79 FR 35920 (June 25, 2014), and the revised Commission Handbook on E-filing, available from the Commission’s website at https://edis.usitc.gov.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is
JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference Committee on Rules of Practice and Procedure

AGENCY: Judicial Conference of the United States, Committee on Rules of Practice and Procedure.

ACTION: Notice of open meeting.

SUMMARY: The Committee on Rules of Practice and Procedure will hold a meeting on January 3, 2019. The meeting will be open to public observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: http://www.uscourts.gov/rules-policies/records-and-archives-committees/agenda-books.

DATES: January 3, 2019.

TIME: 9:00 a.m. to 5:00 p.m.

ADDRESSES: Arizona Biltmore, Sedona Conference Room, 2400 East Missouri Avenue, Phoenix, AZ 85016.

FOR FURTHER INFORMATION CONTACT: Rebecca A. Womeldorf, Rules Committee Secretary, Rules Committee Staff, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.


Rebecca A. Womeldorf,
Rules Committee Secretary.

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Trade Adjustment Assistance Community College and Career Training Grant Program Reporting Requirements

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) revision titled, “Trade Adjustment Assistance Community College and Career Training Grant Program Reporting Requirements” to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before October 26, 2018.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov website at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201807-1205-003 or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to DOL_PRA_PUBLIC@dol.gov.

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: OIRA_submission@omb.eop.gov. Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW, Washington, DC 20210; or by email: DOL_PRA_PUBLIC@dol.gov.

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the Trade Adjustment Assistance Community College and Career Training Grant Program Reporting Requirements information collection. There were four (4) rounds of TAACCT grants originally included under this collection, and the fourth and final round of grants is still active. This information collection has been classified as a revision, because of minor clarifications to the forms (e.g., renaming them) designed to eliminate confusion.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1205–0489. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the Federal Register on February 2, 2018 (83 FR 4926).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the ADDRESSES section within thirty (30) days of publication of this notice in the Federal Register. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0489. The OMB is particularly interested in comments that:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

• Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Enhance the quality, utility, and clarity of the information to be collected; and

• Minimize the burden of the collection of information on those who are to respond, including through the use of alternative automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Trade Adjustment Assistance Community College and Career Training Grant Program Reporting Requirements.

OMB Control Number: 1205–0489.

AFFECTED PUBLIC: Private Sector—businesses or other for-profits and not-for-profit institutions.
NATIONAL SCIENCE FOUNDATION

Request for Information on Update to the 2016 National Artificial Intelligence Research and Development Strategic Plan

AGENCY: Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO), National Science Foundation.

ACTION: Notice of Request for Information.

SUMMARY: On behalf of the National Science and Technology Council’s (NSTC) Select Committee on Artificial Intelligence (Select Committee), NITRD NCO requests input from all interested parties on the National Artificial Intelligence Research and Development Strategic Plan. Through this Request for Information (RFI), NITRD NCO seeks input from the public, including those directly performing Artificial Intelligence (AI) research and development (R&D) and directly affected by such R&D, on whether the strategic plan should be revised and, if so, the ways in which it may be improved. This includes suggestions as to the addition, removal, or modification of strategic aims, comments as to existing strategic aims as well as their past or future implementation by the Federal government. The public input provided in response to this RFI will inform NITRD NCO and the Select Committee in updating the National Artificial Intelligence Research and Development Strategic Plan.

DATES: Interested persons are invited to submit comments on or before 11:59 p.m. (ET) on October 26, 2018.

ADDITIONAL INFORMATION: Comments submitted in response to this notice may be sent by any of the following methods:

- Email: AI-RFI@nitrd.gov. Email submissions should be machine-readable and not be copy-protected. Submissions should include “RFI Response: National Artificial Intelligence Research and Development Strategic Plan” in the subject line of the message.
- Fax: (202) 459–9673, Attn: Faisal D’Souza; or
- Mail: Attn: Faisal D’Souza, NCO, 2415 Eisenhower Avenue, Alexandria, VA 22314, USA.

Instructions: Response to this RFI is voluntary. Each individual or institution is requested to submit only one response. Submissions must not exceed 10 pages in 12 point or larger font, with a page number provided on each page. Responses should include the name of the person(s) or organization(s) filing the comment.

Responses to this RFI may be posted online at http://www.nitrd.gov. Therefore, we request that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI.

In accordance with FAR 15.202(3), responses to this notice are not offers and cannot be accepted by the Government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RFI.

FOR FURTHER INFORMATION CONTACT: Faisal D’Souza at (202) 459–9674 or AI-RFI@nitrd.gov, or by post mailing to 2415 Eisenhower Avenue, Alexandria, VA 22314, USA. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background: In 2016, the National Artificial Intelligence Research and Development Strategic Plan was released by NITRD to guide government efforts in AI research. The plan called for seven strategic aims:

- Strategy 1: Make long-term investments in AI research.
- Strategy 3: Understand and address the ethical, legal, and societal implications of AI.
- Strategy 4: Ensure the safety and security of AI systems.
- Strategy 5: Develop shared public datasets and environments for AI training and testing.
- Strategy 6: Measure and evaluate AI technologies through standards and benchmarks.
- Strategy 7: Better understand the national AI R&D workforce needs.

Subsequently, on May 10, 2018, the White House chartered the Select Committee under the NSTC in order to improve the coordination of Federal efforts related to AI and ensure continued U.S. leadership in AI.

Because AI is a cutting-edge technology with realized or potential impact on many parts of society and science, and both the private sector and the Federal government continue to invest heavily in AI Research and Development (R&D), NITRD NCO and the Select Committee seek to update the strategic plan to reflect current priorities. Following the receipt of comments, the Select Committee, in consultation with the NSTC Subcommittee on Machine Learning and AI (MLAI) and the NITRD AI R&D Interagency Working Group, will consider the input provided in updating the strategic plan.


Submitted by the National Science Foundation in support of the Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) on September 21, 2018.

Suzanne H. Plimpton,
Reports Clearance Officer, National Science Foundation.

NATIONAL TRANSPORTATION SAFETY BOARD

Sunshine Act Meetings

TIME AND DATE: 9:30 a.m., Tuesday, October 16, 2018.

PLACE: NTSB Conference Center, 429 L’Enfant Plaza SW, Washington, DC 20594.

STATUS: The one item is open to the public.


CONTACT PERSON FOR MORE INFORMATION: Candi Bing at (202) 314–6403 or by email at bingc@ntsb.gov.

For Media Information Contact: Terry Williams at (202) 314–6100 or by email at terry.williams@ntsb.gov.

News Media Contact: Telephone: (202) 314–6100.

The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle McCallister at (202) 314–6305 or by email at Rochelle.McCallister@ntsb.gov by Wednesday, September 19, 2018.
The ACRS Subcommittee on Planning and Procedures will hold a meeting on October 3, 2018, 11545 Rockville Pike, Room T–2B1, Rockville, Maryland 20852. The meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

10:15 a.m.–12 p.m.—Annual Operating Reactor Experience Briefing (Open)—The Committee will have an opening remarks regarding the conduct of the meeting.

8:30 a.m.–10 a.m.—Future ACRS Activities/Report of the Planning and Procedures Subcommittee and Reconciliation of ACRS Comments and Recommendations (Open/Closed)—The Committee will hear discussion of the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS meetings. [Note: A portion of this meeting may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

10:15 a.m.–11:30 a.m.—Preparation of ACRS Report (Open)—The Committee will continue its discussion of proposed ACRS report.

1 p.m.–6 p.m.—Preparation of ACRS Report (Open)—The Committee will continue its discussion of proposed ACRS report.

Note: A portion of this meeting may be closed pursuant to 5 U.S.C. 552b(c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

Procedures for the conduct of and participation in ACRS meetings were published in the Federal Register on October 4, 2017 (82 FR 46312). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements and/or written comments should notify the Designated Federal Official (DFO), Quynh Nguyen (Telephone 301–415–5844 or Email: Quynh.Nguyen@nrc.gov) five days prior to the meeting, if possible, so that arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. The public bridge number for the meeting is 866–622–3032, passcode 8272423. Detailed procedures for the conduct of and participation in ACRS meetings were published in the Federal Register on October 4, 2017 (82 FR 46312).
meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience. The bridgeline number for the meeting is 866-822-3032, passcode 8272423#

Thirty-five hard copies of each presentation or handout should be provided 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Cognizant ACRS Staff one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the Cognizant ACRS Staff with a CD containing each presentation at least 30 minutes before the meeting.

In accordance with Subsection 10(d) of Public Law 92–463 and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agendas, meeting transcripts, and letter reports are available through the NRC Public Document Room at pdr.resource@nrc.gov, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC’s document system (ADAMS) which is accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html or http://www.nrc.gov/reading-rm/doc-collections/#ACRS/.

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–6702), between 7:30 a.m. and 3:45 p.m. (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.


Russell E. Chazelle,
Federal Advisory Committee Management Officer, Office of the Secretary.

[FR Doc. 2018–20927 Filed 9–25–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION
[Docket No. 50–331; NRC–2018–0045]

NexEra Energy Duane Arnold, LLC: Duane Arnold Energy Center

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of NexEra Energy Duane Arnold, LLC (NexEra) to withdraw its application dated December 19, 2017, for a proposed amendment to Duane Arnold Energy Center (DAEC), Facility Operating License No. DPR–49. The proposed change would have added Technical Specifications (TS) 3.2.3, “Linear Heat Generation Rate (LHGR),” and modified TS 3.1.1, “Definitions,” TS 3.4.1, “Recirculation Loops Operating,” and TS 5.6.5, “Core Operating Limits Report (COLR)” to reflect the LHGR change. Modifications associated with TS 3.2.1, “Average Planar Linear Heat Generation Rate (APLHGR),” and the new TS 3.2.3 would also have been added to the actions for TS 3.3.4.1, “End of Cycle Recirculation Pump Trip (EOC–RPT) Instrumentation,” and TS 3.7.7, “The Main Turbine Bypass System.” Subsequently, by letter dated August 21, 2018, NexEra withdrew the amendment request.

DATES: The applicable date of the withdrawal of the license amendment application is September 26, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0045 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 http://www.regulations.gov and search for Docket ID NRC–2018–0045. Address questions about NRC dockets 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 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. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• 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 NRC has granted the request of NexEra to withdraw its December 19, 2017 (ADAMS Accession No. ML17353A928), application for proposed amendment to DAEC, Facility Operating License No. DPR–49, located in Linn County, Iowa.

The proposed change would have added TS 3.2.3, “Linear Heat Generation Rate (LHGR),” and modified TS 3.1.1, “Definitions,” TS 3.4.1, “Recirculation Loops Operating,” and TS 5.6.5, “Core Operating Limits Report (COLR)” to reflect the LHGR change. Modifications associated with TS 3.2.1, “Average Planar Linear Heat Generation Rate (APLHGR),” and the new TS 3.2.3 would also have been added to the actions for TS 3.3.4.1, “End of Cycle Recirculation Pump Trip (EOC–RPT) Instrumentation,” and TS 3.7.7, “The Main Turbine Bypass System.”

The Commission had previously issued a notice of consideration of issuance of amendment published in the Federal Register on March 13, 2018 (83 FR 10920). However, by letter dated August 21, 2018, the licensee withdrew the proposed change (ADAMS Accession No. ML18233A333).

For further details with respect to this action, see the application for amendment dated December 19, 2017, and the licensee’s letter dated August 21, 2018, which withdrew the application for license amendment.

Dated at Rockville, Maryland, this 21st day of September, 2018.
I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0063 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 Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-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. The supporting statement associated with the information collections for the policy statement is available in ADAMS under Accession No. ML18171A396.
- 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.
- NRC’s Clearance Officer: A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC’s Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: INFOCOLLECTS.Resource@nrc.gov.

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at http://www.regulations.gov and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information. If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information. 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 submissions into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB’s approval for the information collection summarized below.

1. The title of the information collection: Cooperation With States at Commercial Nuclear Power Plants and Other Nuclear Production and Utilization Facilities.

2. OMB approval number: 3150–0163.

3. Type of submission: Revision.

4. The form number, if applicable: Not applicable.

5. How often the collection is required or requested: On occasion, when a State or federally recognized Indian Tribe wishes to observe NRC inspections or perform inspections for the NRC or when a State or federally recognized Indian Tribe wishes to negotiate an agreement to observe or perform inspections. States with an instrument of cooperation or a State Resident Engineer have both regular reporting and occasion-specific reporting.

6. Who will be required or asked to respond: States and federally recognized Tribes interested in observing or performing inspections.

7. The estimated number of annual responses: 209.

8. The estimated number of annual respondents: 33.

9. The estimated number of hours needed annually to comply with the information collection requirement or request: 1,309 hours.

10. Abstract: States and federally recognized Indian Tribes are involved and interested in monitoring the safety status of nuclear power plants and other nuclear production and utilization facilities. This involvement is, in part, in response to the States’ and Tribes’ public health and safety responsibilities and, in part, in response to their citizens’ desire to become more knowledgeable about the safety of nuclear power plants and other nuclear production and utilization facilities. States and Tribes have identified NRC inspections as one possible source of knowledge for their personnel regarding NRC licensee activities, and the NRC, through the policy statement, “Cooperation With States at Commercial Nuclear Power Plants and Other Nuclear Production or Utilization Facilities” (57
FR 6462; February 25, 1992), has been amenable to accommodating States’ and Tribes’ needs in this regard. The NRC uses the information collected under this information collection requirement to allow States and federally recognized Indian Tribes to participate in or observe inspections at NRC-licensed facilities. The types of information collected include written requests identifying specific inspections States and Tribes wish to observe; identification-related information required for site access to NRC-licensed facilities; training and qualifications of State and Tribal personnel participating in inspections; information required to define inspection roles for States and Tribes; and information to coordinate NRC and State and Tribal inspections.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 21st day of September, 2018.

For the Nuclear Regulatory Commission.

David Cullison,
NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2018–20934 Filed 9–25–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0131]

Monitoring the Effectiveness of Maintenance at Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 4 to Regulatory Guide (RG) 1.160, “Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.” Regulatory Guide 1.160, Revision 4, has been revised to address new issues identified since Revision 3 of RG 1.160 was issued. This RG endorses, with clarifications, NUMARC 93–01, “Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.” Revision 4F. The proposed revision describes methods that are acceptable to the NRC staff for compliance with the requirements for monitoring the effectiveness of maintenance at nuclear power plants.

DATES: Revision 4 to RG 1.160 is available on September 26, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0131 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 http://www.regulations.gov and search for Docket ID NRC–2018–0131. Address questions about NRC dockets to Jennifer Borges; telephone: 301–287–9127; email: Jennifer.Borges@nrc.gov. For technical questions, contact the individuals 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 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. Revision 4 to RG 1.160 and the regulatory analysis may be found in ADAMS under Accession Nos. ML18220B281 and ML18129A085 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, 1155 Rockville Pike, Rockville, Maryland 20852. Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision to an existing guide in the NRC’s “Regulatory Guide” series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency’s regulations, techniques that the NRC staff uses in evaluating specific issues or postulated events, and data that the NRC staff needs in its review of applications for permits and licenses.

Revision 4 of RG 1.160 was issued with a temporary identification of Draft Regulatory Guide, DG–1336. This revision of the guide addresses new issues identified since the guide was previously issued and updates the guidance by endorsing Revision 4F of NUMARC 93–01, “Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.” NUMARC 93–01, Revision 4F addresses the application of the Maintenance Rule (title 10 of the Code of Federal Regulations (CFR) section 50.65) to address the use of diverse and flexible coping strategies.

II. Additional Information

The NRC published a notice of the availability of DG–1336 in the Federal Register on June 28, 2018 (83 FR 30469) for a 30-day public comment period. The public comment period closed on July 30, 2018. Public comments on DG–1336 and the staff responses to the public comments are available under ADAMS under Accession No. ML18220B279.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting and Issue Finality

This RG describes methods acceptable to the staff of the NRC for demonstrating compliance with the provisions of 10 CFR 50.65, “Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants,” of 10 CFR part 50, “Domestic Licensing of Production and Utilization Facilities.” Issuance of this RG does not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and is not otherwise inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the “Implementation” section of this RG, the NRC has no current intention to impose this guidance on holders of current operating licenses or combined licenses. This RG may be applied to applications for amendments to operating licenses or combined licenses.
The Commission notices 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: September 28, 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 FOR FURTHER INFORMATION CONTACT section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

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.

II. Docketed Proceeding(s)

1. Docket No(s): CP2017–254; Filing Title: Notice of the United States Postal Service of Filing Modification Two to a Global Plus 1D Negotiated Service Agreement; Filing Acceptance Date: September 20, 2018; Filing Authority: 39 CFR 3015.5; Public Representative: Christopher C. Mohr; Comments Due: September 28, 2018.

This Notice will be published in the Federal Register.

Stacy L. Ruble, Secretary.

[FR Doc. 2018–20964 Filed 9–25–18; 8:45 am]
BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Nasdaq ISSE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Risk Protections

September 20, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”), and Rule 19b–4 thereunder, notice is hereby given that on September 11, 2018, Nasdaq ISSE, LLC (“ISE” or “Exchange”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend ISE Rules 100(a)(5) which contains definitions, Rule 711, “Acceptance of Quotes and Orders” and Rule 714, “Automatic Execution of Orders”.

The text of the proposed rule change is available on the Exchange’s website at http://ise.cchwallstreet.com/, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

ISE proposes to amend Rule 714, Automatic Execution of Orders, by placing all risk protections within this rule and further creating sections to distinguish order protections, order and quote protections and quote protections. The Exchange believes that providing Members with a single rule with all risk protections will provide an easy reference to the mandatory single leg risk protections on ISE. The Exchange is amending the first sentence of the rule to indicate that the information contained in Rule 714 applies to single leg orders. The Exchange is amending Rule 714(b) to rename the caption from “Other Order Protections” to “Other Single Leg Risk Protections.” The Exchange is amending references to “order protections” to “risk protections” within that rule to more broadly describe the type of protections offered on ISE. Finally, the Exchange is relocating rule text from Rule 714(c) to the end of proposed Rule 714(b), which states, “In the event of unusual market conditions and in the interest of a fair and orderly market, the Exchange may establish the levels at which the order protections contained in this paragraph are triggered as necessary and appropriate.” These non-substantive rule changes are intended to bring greater clarity to the rule.

The Exchange proposes to add the following to proposed Rule 714(b)(1), “The following are order risk protections on ISE.” The Exchange proposes to list all order protections within Rule 714(b)(1). The Exchange proposes to relocate Limit Order Price Protection from Rule 714(b)(2) to proposed Rule 714(b)(1)(A). The Exchange also proposes to add a new sentence to the end of proposed Rule 714(b)(1)(A) which provides, “Limit Order Price Protection shall not apply to the Opening Process or during a trading halt.” The Exchange is adding this sentence, which was not contained in the initial rule change, to make clear the limitations as to when this protection is available on ISE. The Exchange notes the Limit Order Price Protection rejects orders to buy (sell) as the greater of the Exchange’s best offer (bid) plus (minus) either an absolute dollar or a percentage. The Exchange notes that the bid or offer is not established until after an option series options for trading. Applying this protection during the Opening Process is not necessary as the quote width allowance is tighter during the Opening Process. With respect to trading halts, Opening Process procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for a trading halt and the same restrictive boundaries would apply. This sentence memorializes the Exchange’s current practice. The Exchange believes that this rule text will bring greater clarity to the Limit Order Price Protection functionality.

The Exchange proposes to relocate and re-number Market Order Spread Protection from Rule 711(c) to proposed Rule 714(b)(1)(B). The Exchange also proposes to add a sentence which provides, “Market Order Spread Protection shall not apply to the Opening Process or during a trading halt.” The Exchange believes that the Market Order Spread Protection is unnecessary during the Opening Process and during a trading halt because other protections are in place to ensure that the best bid and offer displayed on the Exchange are within a reasonable range. The Exchange is adding this sentence to make clear the limitations as to when this protection is available on ISE. The Exchange believes that this rule text will bring greater clarity to the Market Order Spread Protection functionality.

The Exchange is also memorializing a sentence which was contained in the filing which adopted Market Order Spread Protection. The Exchange noted in the adopting filing that the Exchange may establish differences other than the referenced threshold for one or more series or classes of options. At this time, the Exchange proposes to memorialize this capability within Rule 714(b)(1)(B) by stating, “The Exchange may establish different thresholds for one or more series or classes of options.” The Exchange believes that

3 With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market is based on the best bid and offer of Valid Width Quotes. The differential between the best bid and offer are compared to reach this determination. The allowable differential, as determined by the Exchange, may vary based on the type of security (for example, Standard Penny Issues, Non-Penny Issues and Special Penny Issues), volatility, option premium, and liquidity. The Quality Opening Market differential is intended to ensure the price at which the Exchange opens reflects current market conditions. See ISE Rule 701(a)(7).

4 See note 3 above. With respect to trading halts, Opening Process procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for a trading halt and the same restrictive boundaries would apply. See ISE Rule 701(d).

5 See ISE Rule 701(d).

6 The calculation of Quality Opening Market is based on the best bid and offer of Valid Width Quotes. The differential between the best bid and offer are compared to reach this determination. The allowable differential, as determined by the Exchange, may vary based on the type of security (for example, Standard Penny Issues, Non-Penny Issues and Special Penny Issues), volatility, option premium, and liquidity. The Quality Opening Market differential is intended to ensure the price at which the Exchange opens reflects current market conditions. See ISE Rule 701(a)(7).

adding this provision to the rule will add transparency to the Exchange’s capability to establish different thresholds per options series or class. The Exchange proposes to relocate Size Limitation from Rule 714(b)(3) to proposed Rule 714(b)(1)(C) without any amendments. The Exchange proposes to add the following to proposed Rule 714(b)(2), “The following are order and quote risk protections on ISE”: The Exchange proposes to list all order and quote protections within Rule 714(b)(2). The Exchange proposes to re-letter Acceptable Trade Range from Rule 714(b)(1) to proposed Rule 714(b)(2)(A). The Exchange proposes to relocate Market Wide Risk Protection from Rule 714(d) to proposed Rule 714(b)(1)(D). The Exchange is only amending cross references within this rule to reflect the new location of this text.

The Exchange proposes new rule text at Rule 714(b)(3) which provides, “The following are Market Maker risk protections on ISE”: The Exchange proposes to list all Market Maker protections within Rule 714(b)(3). The Exchange proposes to relocate Anti-Internalization from Supplementary Material .03 to Rule 804 to proposed Rule 714(b)(3)(A). The Exchange proposes to replace the words “market participant identifier” with “Market Maker identifiers.” The Exchange also proposes to replace the words “Exchange account identifier” with “account number.” The Exchange believes these modifications will bring more clarity to the functionality. The Exchange is removing the words “Notwithstanding Rule 804(d)(1) above” which refer to the firm quote. The Exchange notes that the submission of bids and offers must be firm notwithstanding any protection offered by the Exchange, not just Anti-Internalization. The Exchange does not believe it is necessary to specifically cite this caveat for this order protections. The Exchange also proposes to capitalize the defined term Market Maker in this sentence.

The Exchange proposes to relocate Automated Quotation Adjustments from Rule 804(g) to proposed Rule 714(b)(3)(B). Rule 804(g) will be reserved. The Exchange is amending references in the rule to reflect the new placement within Rule 714 and replacing the words “Exchange’s system (“System”)” with the defined term System. Finally, the term “member” was capitalized because it is a defined term. The Exchange is also making clear within Rule 715(b)(3)(B)(vi) that Market Makers must request the Exchange enable re-entry by contacting the Exchange’s Operations Department. Finally, the Exchange proposes to amend the definition of badge within Rule 100(a)(5) to state that a badge is an account number, which may contain letters and/or numbers, assigned to Market Makers. The Exchange may from time to time modify the manner in which a badge is expressed systemically. This proposed language allows for latitude in establishing badges within the System.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act, and furthers the objectives of Section 6(b)(5) of the Act, in particular, that 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 grouping the various risk protections into a single rule for ease of reference and adding headers to the rule to make clear whether the risk protection is an order protection, order or quote protection or a protection applicable to Market Makers. The Exchange believes the reorganization of the existing rule and relocation of various rules into Rule 714 is a non-substantive rule change. The Exchange believes that this rule change is consistent with the protection of investors and the public interest because it will bring greater transparency to the protections offered on ISE. The Exchange’s proposal to not apply the Limit Order Price Protection during the Opening Process is consistent with the Act because the Exchange rejects orders to buy (sell) as the greater of the Exchange’s best offer (bid) plus (minus) either an absolute dollar or a percentage. The Exchange notes that the bid or offer is not established until after an option series options for trading. Applying this protection during the Opening Process is not necessary as the quote width allowance is tighter during the Opening Process. With respect to trading halt during the Opening Process, Open procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for a trading halt and the same restrictive boundaries would apply.

The Exchange’s proposal to not apply the Market Order Spread Protection during the Opening Process is consistent with the Act because protections exist during the Opening Process to ensure that the best bid and offer displayed on the Exchange are within a reasonable range. The Exchange’s Opening Process Rule 701 and the reopening process after a trading halt both contain more restrictive boundaries than those proposed or the Market Order Spread Protection. With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market requires a bid/ask differential applicable to the best bid and offer from all Valid Width Quotes defined in a table to be determined by the Exchange. The Exchange’s requirements during the Opening Process are more restrictive than the proposed initial setting for the Market Order Spread Protection, which is set at $5. The same protections noted for the Opening Process above will apply for trading halt. The Exchange believes that the Market Order Spread Protection is unnecessary during the Opening Process and during a trading halt because other protections are in place to ensure that the best bid and offer displayed on the Exchange are within a reasonable range.

Memorializing the ability of the Exchange to establish different Market Order Spread Protection thresholds per options series or class will also bring greater clarity to the rule. Today, the Exchange has this ability, it is simply adding that text to the rule. Utilizing defined terms within the Rulebook will also bring clarity to the rules. The Exchange also believes using more discrete language within the Anti-Internalization rule will clarify the functionality.

Finally, the Exchange believes that expanding the definition of a badge is consistent with the Act because it

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9 An “account number” shall mean a number assigned to a Member. Members may have more than one account number. See Rule 100(a)(1).
10 ISE Rule 804(d)(1) provides that Market Maker bids and offers are firm for orders and Exchange Market Maker quotations both under this Rule and Rule 602 of Regulation NMS under the Exchange Act (“Rule 602 of Reg NMS”) for the number of contracts specified according to the requirements of paragraph 804(b).
11 The term “System” means the electronic system operated by the Exchange that receives and disseminates quotes, executes orders and reports transactions. See Rule 100(a)(63).
14 See note 3 above.
15 See ISE Rule 701(d).
16 See note 3 above.
17 With respect to trading halt during the Opening Process, Open procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for a trading halt and the same restrictive boundaries would apply. See ISE Rule 701(d).
18 The table is located at: https://business.nasdaq.com/media/ISESystemSettings_tcm5044-44183.pdf.
allows the Exchange the flexibility to administer the badges within its System.

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 proposal does not impose an intra-market burden on competition with respect to the reorganization and relocation of the various rules contained in Rule 714 because the various risk protections are mandatory and will continue to apply uniformly to all market participants. The Exchange also believes that the addition of specific limitations to both the Limit Order Price Protection and Market Order Spread Protection rules will provide market participants with greater information as to when these protections will apply. These limitations apply uniformly to all market participants. The remainder of the rule changes are intended to bring greater transparency to the current operation of the Exchange’s rules.

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) of the Act and Rule 19b–4(f)(6) thereunder.20

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)22 permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange argues that waiver of the operative delay would allow the Exchange to immediately incorporate all risk protections into Rule 714 and bring greater transparency to the risk protections offered on the Exchange. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.23

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 change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (http://www.sec.gov/rules/sro.shtml); or

- Send an email to rule-comments@sec.gov. Please include File Number SR–ISE–2018–80 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–ISE–2018–80. 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 have available publicly. All submissions should refer to File Number SR–ISE–2018–80, and should be submitted on or before October 17, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.24

Brent J. Fields,
Secretary.

[FR Doc. 2018–20881 Filed 9–25–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 33243; File No. 812–14892]

Ares Credit and Income Trust and Ares Capital Management III LLC; Notice of Application

September 21, 2018.

AGENCY: Securities and Exchange Commission (“Commission”).

ACTION: Notice.

Notice of an application for an order under section 12(d)(1)(J) of the Investment Company Act of 1940 (the “Act”) for an exemption from sections 12(d)(1)(A), (B), and (C) of the Act and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (2) of the Act. The requested order would permit certain registered open-end investment companies to acquire shares of certain registered open-end

23 For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).
investment companies, registered closed-end investment companies, business development companies, as defined in section 2(a)(48) of the Act, and registered unit investment trusts (collectively, “Underlying Funds”) that are within and outside the same group of investment companies as the acquiring investment companies, in excess of the limits in section 12(d)(1) of the Act.

APPLICANTS: Ares Credit and Income Trust (the “Trust”), a Delaware statutory trust that will be registered under the Act as an open-end management investment company with multiple series, and Ares Capital Management III LLC (the “Initial Adviser”), a Delaware limited liability company registered as an investment adviser under the Investment Advisers Act of 1940.

FILING DATES: The application was filed on April 3, 2018 and amended on August 3, 2018.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission’s Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on October 16, 2018, and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission’s Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

FOR FURTHER INFORMATION CONTACT: Matthew B. Archer-Beck, Senior Counsel, at (202) 551–5044, or Kaitlin C. Bottoc, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel’s Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission’s website by searching for the file number, or for an applicant using the Company name box, at http://www.sec.gov/search/search.htm, or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order to permit (a) a Fund 1 (each a “Fund of Funds”) to acquire shares of Underlying Funds 2 in excess of the limits in sections 12(d)(1)(A) and (C) of the Act and (b) the Underlying Funds that are registered open-end investment companies or series thereof, their principal underwriters and any broker or dealer registered under the Securities Exchange Act of 1934 to sell shares of the Underlying Fund to the Fund of Funds in excess of the limits in section 12(d)(1)(B) of the Act. 3 Applicants also request an order of exemption under sections 6(c) and 17(b) of the Act from the prohibition on certain affiliated transactions in section 17(a) of the Act to the extent necessary to permit the Underlying Funds to sell their shares to, and redeem their shares from, the Funds of Funds.4 Applicants state that such transactions will be consistent with the policies of each Fund of Funds and each Underlying Fund, consistent with the general purposes of the Act and will be based on the net asset values of the Underlying Funds.

2. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the application. Such terms and conditions are designed to, among other things, help prevent any potential (a) undue influence over an Underlying Fund that is not in the same “group of investment companies” as the Fund of Funds through control or voting power, or in connection with certain services, transactions, and underwritings, (b) excessive layering of fees, and (c) overly complex fund structures, which are the concerns underlying the limits in section 12(d)(1)(A), (B), and (C) of the Act.

3. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

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1 Applicants request that the order apply to each existing and future series of the Trust and to each existing and future registered open-end management investment company or series thereof that is advised by Initial Adviser or its successor-in-interest or by any other investment adviser controlling, controlled by or under common control with the Initial Adviser or its successor-in-interest and is part of the same “group of investment companies” as the Trust (each, a “Fund”). For purposes of the requested order, “successor-in-interest” is limited to an entity that results from a reorganization into another jurisdiction or a change in the type of business organization. For purposes of the request for the term “group of investment companies,” as defined in Section 12(d)(1)(C)(iii) of the Act, means any two or more registered investment companies, including closed-end investment companies and business development companies, that hold themselves out to investors as related companies for purposes of investment and investor services.

2 Certain of the Underlying Funds have obtained exemptions from the Commission necessary to permit their shares to be listed and traded on a national securities exchange at negotiated prices and, accordingly, to operate as an exchange-traded fund (“ETF”).

3 Applicants do not request relief for Funds of Funds to invest in reliance on the order in business development companies and registered closed-end investment companies that are not listed and traded on a national securities exchange.

A Fund of Funds generally would purchase and sell shares of an Underlying Fund that operates as an ETF through secondary market transactions rather than through principal transactions with the Underlying Fund. Applicants nonetheless request relief from sections 17(a)(1) and (2) to permit each ETF that is an affiliated person, or an affiliated person of an affiliated person, of a Fund of Funds, to sell shares to or redeem shares from the Fund of Funds. This includes, in the case of ETFs, creations, redemptions, and creations/redeemings of shares of ETFs, the in-kind transactions that accompany such sales and redemptions. Applicants are not seeking relief from section 17(a) for, and the requested relief will not apply to, transactions where an ETF could be deemed an affiliated person, or an affiliated person of an affiliated person, of a Fund of Funds because an investment adviser to the ETF or an entity controlling, or under common control with the investment adviser to the ETF, also is an investment adviser to the Fund of Funds. A Fund of Funds will purchase and sell shares of an Underlying Fund that is a closed-end fund (including a business development company) through secondary market transactions at market prices rather than through principal transactions with the closed-end fund. Accordingly, applicants are not requesting section 17(a) relief with respect to principal transactions with closed-end funds.
SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To List and Trade Shares of SolidX Bitcoin Shares Issued by the VanEck SolidX Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

September 20, 2018.

On June 20, 2018, Cboe BZX Exchange, Inc. ("BZX" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b–4 thereunder, a proposed rule change to list and trade shares of SolidX Bitcoin Shares ("Shares") issued by the VanEck SolidX Bitcoin Trust ("Trust") under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The proposed rule change was published for comment in the Federal Register on July 2, 2018.3

On August 7, 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 As of September 19, 2018, the Commission has received more than 1,400 comment letters on the proposed rule change.6 This order institutes proceedings under Section 19(b)(2)(B) of the Act7 to determine whether to approve or disapprove the proposed rule change.

I. Summary of the Proposal 8

The Exchange proposes to list and trade the Shares under BZX Rule 14.11(e)(4), which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.9 Each Share will represent a fractional undivided beneficial interest in the Trust's net assets. SolidX Management LLC will be the sponsor of the Trust ("Sponsor"). The Trust will be responsible for custody of the Trust's bitcoin. The Bank of New York Mellon will be the Administrator, transfer agent, and the custodian, with respect to cash, of the Trust. Foreside Fund Services, LLC will be the marketing agent in connection with the creation and redemption of baskets of Shares. Van Eck Securities Corporation will provide assistance in the marketing of the Shares.10

According to the Exchange, the investment objective of the Trust is for the Shares to reflect the performance of the price of bitcoin, less the expenses of the Trust's operations. The Trust is not actively managed and will not engage in activities designed to obtain a profit from, or to ameliorate losses caused by, changes in the price of bitcoin.11 The Administrator will generally use the closing price set for bitcoin by the MVIS Bitcoin OTC Index ("MVBITCO") to calculate the Fund's NAV on each business day that the Exchange is open for regular trading, as promptly as practicable after 4:00 p.m. E.T.12

According to the Exchange, the MVBITCO represents the value of one bitcoin in U.S. dollars at any point in time. The Exchange represents that the MVBITCO calculates the intra-day price of bitcoin every 15 seconds and a closing price as of 4:00 p.m. E.T., each weekday and that the intra-day levels of the MVBITCO incorporate the real-time price of bitcoin based on executable bids and asks derived from constituent bitcoin over-the-counter ("OTC") platforms that have entered into an agreement with MV Index Solutions GmbH ("MVIS") to provide such information. According to the Exchange, the intra-day price and closing level of the MVBITCO is calculated using a proprietary methodology collecting executable bid/ask spread data and calculating a mid-point price from several U.S.-based bitcoin OTC platforms. The Exchange represents that bitcoin OTC platforms included in the MVBITCO are U.S.-based entities that are well established institutions and include entities that are regulated by the Commission and the Financial Industry Regulatory Authority ("FINRA") as registered broker-dealers and affiliates of broker-dealers. According to the Exchange, the logic utilized for the derivations of the intra-day and daily closing index level for the MVBITCO is intended to analyze actual executable bid/ask spread data, verify and refine the data set, and yield an objective, fair-market value of one bitcoin priced in U.S. dollars.13 The Trust’s website will provide an IV per Share updated every 15 seconds, as calculated by the Exchange or a third party financial data provider during the Exchange’s Regular Trading Hours (9:30 a.m. to 4:00 p.m. E.T.).

The Exchange states that the Trust intends to achieve its investment objective by investing substantially all of its assets in bitcoin traded primarily in the OTC markets, but that the Trust may also invest in bitcoin traded on domestic and international bitcoin exchanges, depending on liquidity and other factors at the Trust’s discretion.15

According to the Exchange, the MVBITCO index; (b) the volume-weighted average price over the 24-hour period ending at 4:00 p.m. E.T. as published by a public data feed that is calculated based upon a volume-weighted average bitcoin price obtained from the major U.S. dollar-denominated bitcoin exchanges and that the Sponsor determines is reasonably reliable; and (c) the Sponsor’s best judgment of a good faith estimate of the bitcoin market price. Greater detail concerning the alternative pricing procedures if the MVBITCO cannot be utilized for AV calculations can be found in the Notice. See id. at 31019–20.

1 See id. at 31017–18.

12 See id. at 31023.

13 See id. at 31015.

15 See id. at 31015.

8 The Commission notes that additional information regarding the Trust and the Shares, including investment strategies, calculation of net asset value ("NAV") and intra-day indicative value ("IV"); creation and redemption procedures, and additional background information about bitcoins and the Bitcoin network, among other things, can be found in the Notice (see supra note 3) and the registration statement filed with the Commission on Form S–1 (File No. 333–212479) under the Securities Act of 1933 ("Registration Statement").

9 See BZX Rule 14.11(e)(4) (permitting the listing and trading of “Commodity-Based Trust Shares,” defined as a security (a) that is used by a trust which holds a specified commodity deposited with the trust; (b) that is issued by such trust in a specified aggregate minimum number in return for a deposit of a quantity of the underlying commodity; and (c) that, when aggregated in the same specified minimum number, may be redeemed at a holder’s request by such trust which will deliver to the redeeming holder the quantity of the underlying commodity).

10 See Notice, supra note 3, at 31015.

11 See id. at 31015.

12 See id. at 31020. In the event that the Sponsor determines that this valuation method has failed, the Sponsor will determine the bitcoin market price on the valuation date according to a set of alternative methods to be used in the following order: (a) The mid-point price of the bid/ask spread as of 4:00 p.m. E.T. obtained by the Sponsor from any bitcoin OTC platform that is part of the


16 See id. at 31015.

13See id. at 31023.

14See id. at 31015.

15See id. at 31015.

16 See id. at 31015–18.

17See id. at 31015.

18See id. at 31015.
According to the Exchange, the Trust expects to conduct its trading primarily on the OTC platforms that comprise the MVBTGCO, the Trust also maintains an internal proprietary database, which it does not share with anyone, of potential OTC bitcoin trading counterparties, including hedge funds, family offices, private wealth managers, and high-net-worth individuals. The Exchange represents that all such potential counterparties will be subject to the Trust’s anti-money laundering (“AML”) and know your customer (“KYC”) compliance procedures.

According to the Exchange, the Trust will begin trading with such potential OTC counterparties as their trading capabilities become viable; the Trust will add additional potential counterparties to its internal proprietary database as it becomes aware of additional market participants; and the Trust will decide which OTC counterparties it will trade with based on its ability to fill orders at the best available price among OTC market participants. The Exchange represents that the Trust will provide information regarding the Trust’s bitcoin holdings as well as additional data regarding the Trust. According to the Exchange, investors and market participants will be able throughout the trading day to compare the market price of the Shares to the Shares’ IIV.

According to the Exchange, the Trust will issue and redeem “Baskets,” each equal to a block of 5 Shares. The creation and redemption of a Basket will require the delivery to the Trust, or distribution by the Trust, of the number of whole and fractional bitcoins or the U.S. dollar equivalent represented by each Basket being created or redeemed. Only “Authorized Participants” may place orders to create and redeem Baskets. According to the Exchange, the Trust will not normally hold cash or any other assets, but may hold a very limited amount of cash in connection with the creation and redemption of Baskets and to pay the Trust’s expenses.

The Exchange represents that, in addition to its security system, the Trust will maintain comprehensive insurance coverage underwritten by various insurance carriers. The purpose of the insurance is to protect investors against loss or theft of the Trust’s bitcoin. The Exchange represents that the insurance will cover loss of bitcoin by, among other things, theft, destruction, bitcoin in transit, computer fraud, and other loss of the private keys that are necessary to access the bitcoin held by the Trust, subject to certain terms, conditions, and exclusions that are discussed in the Registration Statement.

According to the Exchange, the Trust will provide information regarding the Trust’s bitcoin holdings as equal to a block of 5 Shares. The Exchange, to the extent the value of the Trust’s bitcoin holdings exceeds the total $125,000,000 of insurance coverage, the Sponsor has made arrangements for additional insurance coverage with the goal of maintaining insurance coverage at a one-to-one ratio with the Trust’s bitcoin holdings valued in U.S. dollars, such that for every dollar of bitcoin held by the Trust there is an equal amount of insurance coverage.

According to the Exchange, the Trust will commence delisting proceedings for a series of Commodity-Based Trust Shares where the applicable trust has fewer than 50,000 receipts or the market value of all receipts issued and outstanding is less than $1,000,000, respectively, following the initial 12 month period following commencement of trading on the Exchange. The Exchange is proposing that BZX Rules 14.11(e)(4)(E)(ii)(b) and (c) provide that the Exchange will commence delisting proceedings for a series of Commodity-Based Trust Shares where the applicable trust has fewer than 50,000 receipts or the market value of all receipts issued and outstanding is less than $1,000,000, respectively, following the initial 12 month period following commencement of trading on the Exchange. The Exchange further asserts that the OTC desks that comprise the MVBTGCO with which the Trust intends to effect transactions are well established institutions that comply with AML and KYC regulatory requirements with respect to trading counterparties and include entities that are regulated by the Commission and FINRA as registered broker-dealers and affiliates of broker-dealers. According to the Exchange, it is the Sponsor’s position that the OTC desks have a better measure of the market than any exchange-specific reference price, whether individually or indexed across multiple exchanges.

The Exchange argues that the geographically diverse and continuous nature of bitcoin trading makes it difficult and prohibitively costly to manipulate the price of bitcoin and that, in many instances, the bitcoin market is generally less susceptible to manipulation than the equity, fixed income, and commodity-futures markets. The Exchange submits a number of arguments for why this is the case, asserting that there is no inside participation to manipulate the bitcoin market or the price of the Shares, and that the Trust’s arbitrage mechanism will facilitate the correction of price discrepancies between bitcoin and the Shares. The Exchange states that the Sponsor believes that demand from new, larger investors accessing bitcoin through investment in the Shares will broaden the investor base in bitcoin, which could further reduce the possibility of collusion among market participants to manipulate the bitcoin market, and that the Sponsor expects that the Shares will be purchased primarily by institutional and other substantial investors (such as hedge funds, family offices, private wealth managers, and high-net-worth individuals), which will provide additional liquidity and transparency to the bitcoin market in a regulated vehicle such as the Trust.

The Exchange also asserts that the policy concerns related to an underlying reference asset and its susceptibility to manipulation are mitigated as it relates to bitcoin because the very nature of the bitcoin ecosystem makes manipulation of bitcoin difficult. The Exchange argues that, particularly, in the OTC markets, the dual elements of principal-to-principal trading combined with the large size at which trades are effected should effectively eliminate the ability of market participants to manipulate the market with small trades as may be the case on any individual exchange. The Exchange further asserts that the OTC desks that comprise the MVBTGCO with which the Trust intends to effect transactions are well established institutions that comply with AML and KYC regulatory requirements with respect to trading counterparties and include entities that are regulated by the Commission and FINRA as registered broker-dealers and affiliates of broker-dealers. According to the Exchange, it is the Sponsor’s position that the OTC desks have a better measure of the market than any exchange-specific reference price, whether individually or indexed across multiple exchanges.

The Exchange argues that the geographically diverse and continuous nature of bitcoin trading makes it difficult and prohibitively costly to manipulate the price of bitcoin and that, in many instances, the bitcoin market is generally less susceptible to manipulation than the equity, fixed income, and commodity-futures markets. The Exchange submits a number of arguments for why this is the case, asserting that there is no inside participation to manipulate the bitcoin market or the price of the Shares, and that the Trust’s arbitrage mechanism will facilitate the correction of price discrepancies between bitcoin and the Shares. The Exchange states that the Sponsor believes that demand from new, larger investors accessing bitcoin through investment in the Shares will broaden the investor base in bitcoin, which could further reduce the possibility of collusion among market participants to manipulate the bitcoin market, and that the Sponsor expects that the Shares will be purchased primarily by institutional and other substantial investors (such as hedge funds, family offices, private wealth managers, and high-net-worth individuals), which will provide additional liquidity and transparency to the bitcoin market in a regulated vehicle such as the Trust.

The Exchange also asserts that the policy concerns related to an underlying reference asset and its susceptibility to manipulation are mitigated as it relates to bitcoin because the very nature of the bitcoin ecosystem makes manipulation of bitcoin difficult. The Exchange argues that, particularly, in the OTC markets, the dual elements of principal-to-principal trading combined with the large size at which trades are effected should effectively eliminate the ability of market participants to manipulate the market with small trades as may be the case on any individual exchange. The Exchange further asserts that the OTC desks that comprise the MVBTGCO with which the Trust intends to effect transactions are well established institutions that comply with AML and KYC regulatory requirements with respect to trading counterparties and include entities that are regulated by the Commission and FINRA as registered broker-dealers and affiliates of broker-dealers. According to the Exchange, it is the Sponsor’s position that the OTC desks have a better measure of the market than any exchange-specific reference price, whether individually or indexed across multiple exchanges.
information about revenue, earnings, corporate activities, or sources of supply; that it is generally not possible to disseminate false or misleading information about bitcoin in order to manipulate; that manipulation of the price on any single venue would require manipulation of the global bitcoin price in order to be effective; that a substantial OTC market provides liquidity and shock-absorbing capacity; that bitcoin’s 24/7/365 nature provides constant arbitrage opportunities across all trading venues; and that it is unlikely that any one actor could obtain a dominant market share.25

Further, the Exchange asserts that bitcoin is arguably less susceptible to manipulation than other commodities that underlie exchange-traded products (“ETPs”) because there may be inside information relating to the supply of the physical commodity (such as the discovery of new sources of supply or significant disruptions at mining facilities that supply the commodity) that simply are not applicable to bitcoin. Further, the Exchange asserts that the fragmentation across bitcoin platforms, the relatively slow speed of transactions, and the capital necessary to maintain a significant presence on each trading platform make manipulation of bitcoin prices through continuous trading activity unlikely. Moreover, according to the Exchange, the linkage between the bitcoin markets and the presence of arbitrageurs in those markets means that the manipulation of the price of bitcoin on any single venue would require manipulation of the global bitcoin price in order to be effective. The Exchange argues that arbitrageurs must have funds distributed across multiple trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular bitcoin exchange or OTC platform. As a result, asserts the Exchange, the potential for manipulation on a trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences.26

The Exchange asserts that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. According to the Exchange, trading of the Shares through the Exchange will be subject to the Exchange’s surveillance procedures for derivative products, including Commodity-Based Trust Shares. The Exchange further represents that, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will surveil for compliance with the continued listing requirements and that, if the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under BZX Rule 14.12.27

The Exchange represents that it may obtain information regarding trading in the Shares and listed bitcoin derivatives via the Intermarket Surveillance Group (“ISG”), from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, the Exchange represents that it may obtain information about bitcoin transactions, trades, and market data from bitcoin exchanges with which the Exchange has entered into a comprehensive surveillance sharing agreement as well as certain additional information that is publicly available through the Bitcoin blockchain. The Exchange notes that it has entered into a comprehensive surveillance sharing agreement with the Gemini Exchange.28

II. Proceedings To Determine Whether To Approve or Disapprove SR–ChoeBZX–2018–040 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act29 to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described below, the Commission seeks and encourages interested persons to provide comments on the proposed rule change.

Pursuant to Section 19(b)(2)(B) of the Act,30 the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change’s consistency with Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be “designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade,” and “to protect investors and the public interest.”31

The Commission asks that commenters address the sufficiency of the Exchange’s statements in support of the proposal, which are set forth in the Notice,32 in addition to any other comments they may wish to submit about the proposed rule change. In particular, the Commission seeks comment on the following:

1. What are commenters’ views of the Exchange’s assertions that bitcoin is arguably less susceptible to manipulation than other commodities that underlie ETPs; that the geographically diverse and continuous nature of bitcoin trading makes it difficult and prohibitively costly to manipulate the price of bitcoin; that trading on inside information regarding bitcoin is unlikely; that the fragmentation across bitcoin markets, the relatively slow speed of transactions, and the capital necessary to maintain a significant presence on each trading platform make manipulation of bitcoin prices through continuous trading activity unlikely; that manipulation of the price on any single venue would require manipulation of the global bitcoin price to be effective; that a substantial OTC bitcoin market provides liquidity and shock-absorbing capacity; that bitcoin’s 24/7/365 nature provides constant arbitrage opportunities across all trading venues; and that it is unlikely that any one actor could obtain a dominant market share?

2. What are commenters’ views on the Sponsor’s assertion, described by the Exchange in the Notice, that “the OTC desks have a better measure of the market than any exchange-specific reference price, whether individually or indexed across multiple exchanges”? What are commenters’ views on the Exchange’s representation that, in the OTC markets, the dual elements of principal-to-principal trading combined with the large size at which trades are effected should effectively eliminate the ability of market participants to manipulate the market with small trades as may be the case on any individual exchange? What is the current typical number and volume of transactions on the OTC market? What are commenters’ views on whether the liquidity of the OTC bitcoin market, which would be used as the reference market for pricing

25 See id.
26 See id.
27 See id. at 31024–25.
28 See id. at 31025.
30 Id.
32 See Notice, supra note 3.
the proposed ETP’s holdings, is sufficient for efficient bitcoin price discovery? What are commenters’ views on whether the liquidity of the OTC bitcoin market is sufficient to support efficient arbitrage between the price of the Shares and the spot price of bitcoin? What are the numbers of active traders, market makers, and other liquidity providers on the OTC bitcoin market? To what extent is trading in the OTC bitcoin market subject to regulation?

3. The Exchange asserts that the dissemination of information on the Trust’s website, along with quotations for and last-sale prices of transactions in the Shares and the NAV of the Trust, will help to reduce the ability of market participants to manipulate the bitcoin market or the price of the Shares and that the Trust’s arbitration mechanism will facilitate the correction of price discrepancies in bitcoin and the Shares. In addition, the Exchange asserts that demand from new, larger investors accessing bitcoin through investment in the Shares will broaden the investor base in bitcoin, which could further reduce the possibility of collusion among market participants to manipulate the bitcoin market. The Exchange further states that the exploitation of arbitrage opportunities by Authorized Participants and their clients and customers will tend to cause the public trading price to track NAV per Share closely over time. What are commenters’ views regarding these statements? For example, do commenters agree or disagree with the assertion that Authorized Participants and other market makers will be able to engage in arbitrage and to make efficient and liquid markets in the Shares at prices generally in line with the NAV?

4. What are commenters’ views, generally, on whether the proposed ETP would be susceptible to manipulation?

5. What are commenters’ views on whether and to what extent bitcoin futures markets generally, and current volume on those markets specifically, affect the sustainability of bitcoin to manipulation? What are commenters’ views on whether and to what extent other listed bitcoin derivatives, and the current volume on the markets for those derivatives, affect the sustainability of bitcoin to manipulation?

6. What are commenters’ views on the Trust’s proposal to value its bitcoin holdings based on an index—the MVBTCO—that is calculated through a proprietary, non-public methodology that uses the private bid/ask spreads of an unidentified set of U.S.-based market makers in the OTC bitcoin marketplace, which, the Exchange says, has no formal structure and no open outcry meeting place? Is the use of a non-public proprietary index to value holdings based on OTC activity an appropriate means to calculate the NAV of an ETP? What are commenters’ views on whether determining NAV based on the index value at 4:00 p.m. E.T. might, or might not, create an opportunity for manipulation of the NAV or of the Shares?

7. What are commenters’ views on the statement in the Notice that, according to the Sponsor, the MVBTCO’s methodology decreases the influence on the MVBTCO of any particular OTC platform that diverges from the rest of the data points used by the MVBTCO, which reduces the possibility of an attempt to manipulate the price of bitcoin as reflected by the MVBTCO?

8. What are commenters’ views on each of the set of alternative means by which the Trust proposes to value its holdings in the event that the Sponsor determines that the MVBTCO, or another alternate pricing mechanism, has failed or is unavailable?

9. The Exchange represents that, while the Trust intends to conduct the majority of its trading in the OTC market on the OTC platforms that comprise the MVBTCO, the Trust also will maintain an internal proprietary database, which it will not share with anyone, of potential OTC bitcoin trading counterparties, including hedge funds, family offices, private wealth managers, and high-net-worth individuals. The Exchange further states that OTC bitcoin trading is typically private and not regularly reported, and that the Trust does not intend to report its OTC trading. What are commenters’ views on how the Trust’s unreported OTC trades may affect the calculation of the Trust’s NAV and the ability of market makers to engage in arbitrage?

10. What are commenters’ views on the relationship between trading in the OTC bitcoin market and the wider global bitcoin market? What are commenters’ views on the circumstances pursuant to which the OTC bitcoin market may trade at a premium or discount to the global bitcoin market? What are commenters’ views on whether or not the OTC bitcoin market would provide a measure of insulation from erratic or dislocated trading in the global bitcoin market?

11. What are commenters’ views on the cost and the efficiency of arbitrage across the various global markets for bitcoin? What are commenters’ views generally with respect to the liquidity and transparency of the bitcoin market, the bitcoin markets’ susceptibility to manipulation, and thus the suitability of bitcoin as an underlying asset for an ETP?

12. What are commenters’ views on the Exchange’s representation that the Sponsor estimates that the U.S. dollar OTC bitcoin trading volume globally represents on average approximately 50% of the trading volume of bitcoin traded globally in U.S. dollars on U.S.-dollar-denominated bitcoin exchanges? Is the volume of U.S. dollar trading of bitcoin—which excludes bitcoin trading against other sovereign currencies or digital assets—a meaningful or appropriate measure of bitcoin market volume? Why or why not?

13. What are commenters’ views on whether the Exchange has entered into a surveillance-sharing agreement with a regulated market of significant size related to bitcoin? What are commenters’ views on the current regulation of bitcoin-related markets? What are commenters’ views on whether markets for listed bitcoin derivatives—such as bitcoin futures markets—are markets of significant size? What are commenters’ views on whether there is a reasonable likelihood that a person attempting to manipulate the proposed ETP would also have to trade on a regulated bitcoin-related market with which the Exchange has a surveillance sharing agreement? What are commenters’ views on whether trading in the proposed ETP would be the predominant influence on prices in a regulated, bitcoin-related market with which the Exchange has a surveillance-sharing agreement?

14. The Exchange represents that it has entered into a comprehensive surveillance-sharing agreement with the Gemini Exchange. What are commenters’ views on whether the Gemini Exchange is a market of significant size? What are commenters’ views on whether there is a reasonable likelihood that a person attempting to manipulate the proposed ETP would also have to trade on the Gemini Exchange? What are commenters’ views on whether trading in the proposed ETP would be the predominant influence on prices in the Gemini Exchange?

15. According to the Exchange, the Shares will be purchased primarily by institutional and other substantial investors (such as hedge funds, family offices, private wealth managers, and high-net-worth individuals), which will provide additional liquidity and transparency to the bitcoin market in a regulated vehicle such as the Trust. The Exchange asserts that, with an estimated initial per-share price equivalent to 25 bitcoins, the Shares would be cost-prohibitive for smaller retail investors while allowing larger and generally
more sophisticated institutional investors to gain exposure to the price of bitcoin through a regulated product, eliminating the complications and reducing the risk associated with buying and holding bitcoin. What are commenters’ views of the Exchange’s assertions that transacting in the Shares will be geared toward more sophisticated institutional investors and will be cost-prohibitive for smaller retail investors? What are commenters’ views regarding whether broker-dealers are likely to offer fractional shares in the Trust to retail investors, permitting retail investment with a smaller financial commitment? What are commenters’ views of the Exchange’s assertions that the Sponsor believes that demand from new, larger investors accessing bitcoin through investment in the Shares will broaden the investor base in bitcoin, which could further reduce the possibility of collusion among market participants to manipulate the bitcoin market, in light of the possibility that broker-dealers may offer fractional shares to their customers?

16. The Exchange represents that there will be at least 100 Shares outstanding at the time of commencement of trading on the Exchange and that this amount of Shares outstanding at the commencement of trading will be sufficient to provide adequate market liquidity. What are commenters’ views on the Exchange’s assertion that a minimum of 100 Shares outstanding at the time of commencement of trading will be sufficient to provide adequate market liquidity? What are commenters’ views on whether the 100-share minimum would affect the arbitrage mechanism?

17. What are commenters’ views on the Exchange’s assertion that, even though the Trust would not comply with the minimum number of shares outstanding required by Exchange rules, the policy concerns underlying that requirement would be otherwise mitigated in the case of the Trust, because the lower number of Shares is merely a function of the price of the Shares and will have no effect on the creation and redemption process or on arbitrage?

18. The Exchange states that the Trust will maintain crime, excess crime, and excess vault risk insurance coverage underwritten by various insurance carriers that will cover the entirety of the Trust’s bitcoin holdings. The Exchange further states that, while the Trust is confident in its system for securing its bitcoin, insurance coverage of all of the Trust’s bitcoin holdings eliminates exposure to the risk of loss to investors through fraud or theft, which in turn eliminates most of the custodial issues associated with a series of Commodity-Based Trust Shares based on bitcoin. What are commenters’ views of whether the proposed insurance coverage would affect trading in the Shares or in the underlying bitcoins? What are commenters’ views regarding the Trust’s proposed security, control, and insurance measures?

III. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, and the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4, any request for an opportunity to make an oral presentation.33

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by October 17, 2018. Any person who wishes to file a rebuttal to any other person’s submission must file that rebuttal by October 31, 2018. 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–CboeBZX–2018–040 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–CboeBZX–2018–040. 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 during 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. All submissions should refer to File Number SR–CboeBZX–2018–040 and should be submitted by October 17, 2018. Rebuttal comments should be submitted by October 31, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.34

Brent J. Fields,
Secretary.

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SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations: Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Risk Protections

September 20, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),1 and Rule 19b–4 thereunder,2 the Securities and Exchange Commission ("Commission") approved a proposed rule change with respect to the Nasdaq MRX, LLC ("MRX" or "Exchange") filed with the Commission by Nasdaq MRX, LLC ("Nasdaq MRX," "MRX" or "Exchange") on September 11, 2018, Nasdaq MRX, LLC ("MRX'' or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend MRX Rules 100(a)(5) which contains definitions, Rule 711, “Acceptance of Quotes and Orders” and Rule 714, “Automatic Execution of Orders.” The text of the proposed rule change is available on the Exchange’s website at http://nasdaqmrx.cchwallstreet.com/, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

MRX proposes to amend Rule 714, Automatic Execution of Orders, by placing all risk protections within this rule and further creating sections to distinguish order protections, order and quote protections and quote protections. The Exchange believes that providing Members with a single rule with all risk protections will provide an easy reference to the mandatory single leg risk protections on MRX.

The Exchange is amending Rule 714(b) to rename the caption from “Other Order Protections” to “Other Risk Protections.” The Exchange is amending references to “order protections” and “risk protections” within that rule to more broadly describe the type of protections offered on MRX. Finally, the Exchange is relocating rule text from Rule 714(c) to the end of proposed Rule 714(b), which states, “In the event of unusual market conditions and in the interest of a fair and orderly market, the Exchange may temporarily establish the levels at which the order protections contained in this paragraph are triggered as necessary and appropriate.” These non-substantive rule changes are intended to bring greater clarity to the rule.

The Exchange proposes to add the following to proposed Rule 714(b)(1), “The following are order risk protections on MRX.” The Exchange proposes to list all order protections within Rule 714(b)(1). The Exchange proposes to relocate Limit Order Price Protection from Rule 714(b)(2) to proposed Rule 714(b)(1)(A). The Exchange also proposes to add a new sentence to the end of proposed Rule 714(b)(1)(A) which provides, “Limit Order Price Protection shall not apply to the Opening Process or during a trading halt. The Exchange is adding this sentence, which was not contained in the initial rule change, to make clear the limitations as to when this protection is available on MRX. The Exchange notes the Limit Order Price Protection rejects orders to buy (sell) as the greater of the Exchange’s best offer (bid) plus (minus) either an absolute dollar or a percentage. The Exchange notes that the bid or offer is not established until after an option series options begins trading. Applying this protection during the Opening Process is not necessary as the quote width allowance is tighter during the Opening Process.3 With respect to trading halts, Opening Process procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for a trading halt and the same restrictive boundaries would apply.4 This sentence memorializes the Exchange’s current practice. The Exchange believes that this rule text will bring greater clarity to the Limit Order Price Protection functionality.

The Exchange proposes to relocate and re-number Market Order Spread Protection from Rule 711(c) to proposed Rule 714(b)(1)(B). The Exchange also proposes to add a sentence which provides, “Market Order Spread Protection shall not apply to the Opening Process or during a trading halt.” The Exchange believes that the Market Order Spread Protection is unnecessary during the Opening Process and during a trading halt because protections are in place during the Opening Process to ensure that the best bid and offer displayed on the Exchange are within a reasonable range.5 The Opening Process has more restrictive boundaries than those proposed for the Market Order Spread Protection. With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market requires a bid/ask differential applicable to the best bid and offer from all Valid Width Quotes defined in a table6 to be determined by the Exchange.7 The Exchange’s requirements during the Opening Process are more restrictive than the proposed initial setting for the Market Order Spread Protection, which is proposed at $5. As provided in Rule 701(d), trading halts are subject to the reopening process as provided for in Rule 701(e). The same protections noted for the Opening Process above will apply for trading halts. The Exchange believes that the Market Order Spread Protection is unnecessary during the Opening Process and during a trading halt because other protections are in place to ensure that the best bid and offer displayed on the Exchange are

3 With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market is based on the best bid and offer of Valid Width Quotes. The differential between the best bid and offer are compared to reach this determination. The allowable differential, as determined by the Exchange, takes into account the type of security (for example, Standard Penny Issues, Non-Penny Issues and Special Penny Issues), volatility, option premium, and liquidity. The Quality Opening Market differential is intended to ensure the price at which the Exchange opens reflects current market conditions. See MRX Rule 701(a)(7).

4 See MRX Rule 701(d).

5 See note 3 above. With respect to trading halts, Opening Process procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for trading halt and the same restrictive boundaries would apply. See MRX Rule 701(d).

6 The table is located at: https://business.nasdaq.com/media/MRX/systemSettings_tcm5044-46766.pdf.

7 The calculation of Quality Opening Market is based on the best bid and offer of Valid Width Quotes. The differential between the best bid and offer are compared to reach this determination. The allowable differential, as determined by the Exchange, takes into account the type of security (for example, Standard Penny Issues, Non-Penny Issues and Special Penny Issues), volatility, option premium, and liquidity. The Quality Opening Market differential is intended to ensure the price at which the Exchange opens reflects current market conditions. See MRX Rule 701(a)(7).

8 See MRX Rule 701(d).
within a reasonable range. The Exchange is adding this sentence to make clear the limitations as to when this protection is available on MRX. The Exchange believes that this rule text will bring greater clarity to the Market Order Spread Protection functionality. The Exchange is also memorializing a sentence which was contained in the filing which adopted Market Order Spread Protection.

The Exchange noted in the adopting filing that the Exchange may establish differences other than the referenced threshold for one or more series or classes of options. At this time, the Exchange proposes to memorialize this capability within Rule 714(b)(1)(B) by stating, “The Exchange may establish different thresholds for one or more series or classes of options.” The Exchange believes that adding this provision to the rule will add transparency to the Exchange’s capability to establish different thresholds per options series or class. The Exchange proposes to relocate Size Limitation from Rule 714(b)(3) to proposed Rule 714(b)(1)(C) without any amendments. The Exchange proposes to add the following to proposed Rule 714(b)(2), “The following are order and quote risk protections on MRX:”. The Exchange proposes to list all order and quote protections within Rule 714(b)(2). The Exchange proposes to re-letter Acceptable Trade Range from Rule 714(b)(1) to proposed Rule 714(b)(2)(A).

The Exchange proposes to relocate Market Wide Risk Protection from Rule 714(d) to proposed Rule 714(b)(1)(D). The Exchange is only amending cross references within this rule to reflect the new location of this text. The Exchange proposes new rule text at Rule 714(b)(3) which provides, “The following are Market Maker risk protections on MRX:”. The Exchange proposes to list all Market Maker protections within Rule 714(b)(3). The Exchange proposes to relocate Anti-Internalization from Supplementary Material 03 to Rule 804 to proposed Rule 714(b)(3)(A). The Exchange proposes to replace the words “market participant identifier” with “Market Maker identifiers.” The Exchange also proposes to replace the words “Exchange account identifier” with “account number.” The Exchange believes these modifications will bring more clarity to the functionality. The Exchange is removing the words “Notwithstanding Rule 804(d)(1) above” which refer to the firm quote. The Exchange notes that the submission of bids and offers must be firm notwithstanding any protection offered by the Exchange, not just Anti-Internalization. The Exchange does not believe it is necessary to specifically cite this caveat for this order protections. The Exchange also proposes to capitalize the defined term Market Maker in this sentence.

The Exchange proposes to relocate Automated Quotation Adjustments from Rule 804(g) to proposed Rule 714(b)(3)(B). Rule 804(g) will be reserved. The Exchange is amending references in the rule to reflect the new placement within Rule 714 and replacing the words “Exchange’s system (“System”)” with the defined term System. Finally, the term “member” was capitalized because it is a defined term. The Exchange is also making clear within Rule 715(b)(3)(B)(vi) that Market Maker must request the Exchange enable re-entry by contacting the Exchange’s Operations Department. Finally, the Exchange proposes to amend the definition of badge within Rule 100(a)(5) to state that a badge is an account number, which may contain letters and/or numbers, assigned to Market Makers. The Exchange may from time to time modify the manner in which a badge is expressed systemically. This proposed language allows for latitude in establishing badges within the System.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act, in general, and further the objectives of Section 6(b)(5) of the Act, in particular, in that 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 grouping the various risk protections into a single rule for ease of reference and adding headers to the rule to make clear whether the risk protection is an order protection, order or quote protection or a protection applicable to Market Makers. The Exchange believes the reorganization of the existing rule and relocation of various rules into Rule 714 is a non-substantive rule change. The Exchange believes that this rule change is consistent with the protection of investors and the public interest because it will bring greater transparency to the protections offered on MRX.

The Exchange’s proposal to not apply the Limit Order Price Protection during the Opening Process is consistent with the Act because the Exchange rejets orders to buy (sell) as the greater of the Exchange’s best offer (bid) plus (minus) either an absolute dollar or a percentage. The Exchange notes that the bid or offer is not established until after an option series options for trading. Applying this protection during the Opening Process is not necessary as the quote width allowance is tighter during the Opening Process. With respect to trading halts, Opening Process procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for a trading halt and the same restrictive boundaries would apply.

The Exchange’s proposal to not apply the Market Order Spread Protection during the Opening Process is consistent with the Act because protections exist during the Opening Process to ensure that the best bid and offer displayed on the Exchange are within a reasonable range. The Exchange’s Opening Process Rule 701 and the reopening process after a trading halt both contain more restrictive boundaries than those proposed or the Market Order Spread Protection. With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market requires a bid/ask differential applicable to the best bid and offer from all Valid Width Quotes defined in a table to be determined by the Exchange. The Exchange’s requirements during the Opening Process are more restrictive than the proposed initial setting for the Market Order Spread Protection, which is set at $5. The same protections noted for the Opening Process above will apply.
apply for trading halts. The Exchange believes that the Market Order Spread Protection is unnecessary during the Opening Process and during a trading halt because other protections are in place to ensure that the best bid and offer displayed on the Exchange are within a reasonable range.

Memorializing the ability of the Exchange to establish different Market Order Spread Protection thresholds per options series or class will also bring greater clarity to the rule. Today, the Exchange has this ability, it is simply adding that text to the rule. Utilizing defined terms within the Rulebook will also bring clarity to the rules. The Exchange also believes using more discrete language within the Anti-Internalization rule will clarify the functionality.

Finally, the Exchange believes that expanding the definition of badge is consistent with the Act because it allows the Exchange the flexibility to administer the badges within its System.

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 proposal does not impose an intra-market burden on competition with respect to the reorganization and relocation of the various rules into Rule 714 because the various risk protections are mandatory and will continue to apply uniformly to all market participants. The Exchange also believes that the addition of specific limitations to both the Limit Order Price Protection and Market Order Spread Protection rules will provide market participants with greater information as to when these protections will apply. These limitations apply uniformly to all market participants. The remainder of the rule changes are intended to bring greater transparency to the current operation of the Exchange’s rules.

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) of the Act and Rule 19b–4(f)(6) thereunder.20

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act21 normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(i)(ii)22 permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange argues that waiver of the operative delay would allow the Exchange to immediately incorporate all risk protections into Rule 714 and bring greater transparency to the risk protections offered on the Exchange. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operational delay and designates the proposed rule change operative upon filing.23

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 change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

Comments may be submitted by any of the following methods:

Electronically

• 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–MRX–2018–30 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–MRX–2018–30. 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. All submissions should refer to File Number SR–MRX–2018–30, and should be submitted on or before October 17, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.24

Brent J. Fields,
Secretary.

[FR Doc. 2018–20882 Filed 9–25–18; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Rules Relating to Categories of Registration and Respective Qualification Examinations Required for Members That Engage in Trading Activities on the Exchange

September 20, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”), 1 and Rule 19b–4 thereunder, 2 notice is hereby given that on September 18, 2018, Cboe BYX Exchange, Inc. (“Exchange” or “BYX”) filed with the Securities and Exchange Commission (“Commission”) the proposed rule change as described in Items I and II below, which 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 filed a proposal to amend its rules relating to categories of registration and respective qualification examinations required for Members that engage in trading activities on the Exchange.

The text of the proposed rule change is available at the Exchange’s website at www.markets.cboe.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.


A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The SEC recently approved a proposed rule change to restructure the FINRA representative-level qualification examination program. The rule change, which will become effective on October 1, 2018, restructures the examination program into a more efficient format whereby all new representative-level applicants will be required to take a general knowledge examination (the Securities Industry Essentials Examination (“SIE”)) and a tailored, specialized knowledge examination (a revised representative-level qualification examination) for their particular registered role. Individuals are not required to be associated with an Exchange or any other self-regulatory organization (“SRO”) member to be eligible to take the SIE. However, passing the SIE alone will not qualify an individual for registration with the Exchange. To be eligible for registration, an individual must also be associated with a firm, pass an appropriate qualification examination for a representative or principal and satisfy the other requirements relating to the registration process.

The SIE would assess basic product knowledge; the structure and function of the securities industry markets, regulatory agencies and their functions; and regulated and prohibited practices. In particular, the SIE will cover four major areas. The first, “Knowledge of Capital Markets,” focuses on topics such as types of markets and offerings, broker-dealers and depositories, and economic cycles. The second, “Understanding Products and Their Risks,” covers securities products at a high level as well as associated investment risks. The third, “Understanding Trading, Customer Accounts and Prohibited Activities,” focuses on accounts, orders, settlement and prohibited activities. The final area, “Overview of the Regulatory Framework,” encompasses topics such as SROs, registration requirements and specified conduct rules. It’s anticipated that the SIE would include 75 scored questions plus an additional 10 unscored pretest questions. The passing score would be determined through methodologies compliant with testing industry standards used to develop examinations and set passing standards.

The restructured program eliminates duplicative testing of general securities knowledge on the current representative-level qualification examinations by moving such content into the SIE. The SIE will test fundamental securities related knowledge, including knowledge of basic products, the structure and function of the securities industry, the regulatory agencies and their functions and regulated and prohibited practices, whereas the revised representative-level qualification examinations will test knowledge relevant to day-to-day activities, responsibilities and job functions of representatives. The SIE was developed in consultation with a committee of industry representatives and representatives of several other SROs. Each of the current representative-level examinations covers general securities knowledge, with the exception of the Research Analyst (Series 86 and 87) examinations.

The Exchange proposes to require that effective October 1, 2018, new applicants seeking to register in a representative capacity with the Exchange must pass the SIE before their registrations can become effective. The Exchange proposes to make the requirement operative on October 1, 2018 to coincide with the effective date of FINRA’s requirement.

The Exchange notes that individuals who are registered as of October 1, 2018 are eligible to maintain their registrations without being subject to any additional requirements. Individuals who had been registered within the past two years prior to October 1, 2018, would also be eligible to maintain those registrations without being subject to any additional requirements, provided they register within two years from the date of their last registration. However, with respect to an individual who is not registered on the effective date of the proposed rule change but was registered within the past two years prior to the effective date of the proposed rule change, the individual’s SIE status in the CRD system would be administratively terminated if such individual does not register with the Exchange within four years from the date of the individual’s last registration. The Exchange also notes that consistent with Interpretation and Policy .01(b) of Rule 2.5, the Exchange will consider waivers of the SIE alone or the SIE and the representative or principal-level examination(s) for Members who are
seeking registration in a representative- or principal-level registration category.4 Lastly, the Exchange proposes to eliminate references in its rules to alternative foreign examination modules, along with specific references to the Series 17, 37 and 38 examinations. Particularly, the Exchange notes that FINRA recently announced it was eliminating the United Kingdom Securities Representative and the Canadian Securities Representative registration categories, along with the respective associated exams (i.e., Series 17, Series 37 and Series 38).5 FINRA also stated that it intended to provide individuals who are associated persons of firms and who hold foreign registrations an alternative, more flexible, process to obtain an Exchange representative-level registration.6 The Exchange believes that there is sufficient overlap between the SIE and foreign qualification requirements to permit them to act as exemptions to the SIE. As such, the Exchange proposes to provide that individuals who are in good standing as representatives with the Financial Conduct Authority in the United Kingdom or with a Canadian stock exchange or securities regulator would be exempt from the requirement to pass the SIE, and thus would be required only to pass a specialized knowledge examination to register with the Exchange as a representative. The proposed approach would provide individuals with a United Kingdom or Canadian qualification more flexibility to obtain a representative-level registration. The Exchange notes that FINRA has adopted a similar rule.7

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b)(5) of the Act.8 Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)9 requirements that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange believes that the proposed rule change will improve the efficiency of the Exchange’s examination requirements, without compromising the qualification standards, by eliminating duplicative testing of general securities knowledge on examinations. FINRA has indicated that the SIE was developed in an effort to adopt an examination that would assess basic product knowledge; the structure and function of the securities industry markets, regulatory agencies and their functions; and regulated and prohibited practices. The Exchange also notes that the introduction of the SIE and expansion of the pool of individuals who are eligible to take the SIE, has the potential of enhancing the pool of prospective securities industry professionals by introducing them to securities laws, rules and regulations and appropriate conduct before they join the industry in a registered capacity. Lastly, the Exchange notes adopting the SIE requirement is consistent with the requirement recently adopted by FINRA.10

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change, which harmonizes its rules with recent rule changes adopted by FINRA and which is being filed in conjunction with similar filings by the other national securities exchanges, will reduce the regulatory burden placed on market participants engaged in trading activities across different markets. The Exchange believes that the harmonization of these registration requirements across the various markets will reduce burdens on competition by removing impediments to participation in the national market system and promoting competition among participants across the multiple national securities exchanges.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

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)(4)(A) of the Act11 and Rule 19b–4(f)(6) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days from the date of filing. However, Rule 19b–4(f)(6)(iii)12 permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative on October 1, 2018 to coincide with the effective date of FINRA’s proposed rule change on which the proposal is based.14 The waiver of the operative delay would make the Exchange’s qualification requirements consistent with those of FINRA, as of October 1, 2018. Therefore, the Commission believes that the waiver of the 30-day operative delay is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposal operative on October 1, 2018.15

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

4 Pursuant to a Regulatory Services Agreement between FINRA and the Exchange, FINRA provides the Exchange certain exam waiver services in responding to exam waiver requests from Exchange Members.
6 Id.
7 Id.
10 See supra note 3.
13 See supra note 3.
14 For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).
15 For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).
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 proposal 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 No. SR–CboeBYX–2018–019 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 No. SR–CboeBYX–2018–019. 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. All submissions should refer to File No. SR–CboeBYX–2018–019 and should be submitted on or before October 17, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.16

Brent J. Fields,
Secretary.

[FR Doc. 2018–20878 Filed 9–25–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION


Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Granting Approval of Proposed Rule Change To Codify the Processing of Conditional Prepayment Rate Claims in the MBSD Rules and Make Other Changes

September 20, 2018.

On July 26, 2018, Fixed Income Clearing Corporation (“FICC”) filed with the U.S. Securities and Exchange Commission (“Commission”) proposed rule change SR–FICC–2018–006 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”)1 and Rule 19b–4 thereunder.2 The proposed rule change was published for comment in the Federal Register on August 8, 2018.3 The Commission did not receive any comment letters on the proposed rule change. For the reasons discussed below, the Commission approves the proposed rule change.

I. Description of the Proposed Rule Change

The proposed rule change would make amendments to FICC’s Mortgage-Backed Securities Division (“MBSD”) Clearing Rules (“MBSD Rules”)4 in order to (i) add terms governing MBSD’s current processing of conditional prepayment rate (“CPR”) claims to the MBSD Rules, and (ii) make certain clarifications and corrections in the MBSD Rules, as described below.5

A. CPR Claims

Mortgage pools6 are often traded in To-Be-An annunced (“TBA”) trades, which are trades for which the actual identities of and/or the number of pools underlying each trade are unknown at the time of trade execution.7 MBSD guidelines provide that two business days prior to the established settlement date of the TBA settlement obligations, the FICC MBSD clearing member (“Clearing Member”) that has an obligation to deliver pools for the TBA transaction (i.e., the “seller”) must allocate the pools to be delivered.8 FICC states that pursuant to the MBSD Rules, Clearing Members may substitute an underlying pool after it has been allocated with respect to a pool deliver obligation by providing instructions to FICC.9 CPR is the percentage of the outstanding loan balance for a pool that is expected to be repaid over a one-year period.10 A CPR claim arises when an underlying TBA pool is allocated or substituted with a pool that pays down at a faster rate (i.e., has a higher CPR) than the average pay down rate for pools of the same type as the underlying pool being replaced.11 The result is that the buyer is receiving a pool with less value than anticipated based on the TBA terms.

As provided in the SIFMA Guidelines,12 the industry currently has a process pursuant to which a buyer may make a CPR claim against the seller. The CPR claim process is intended to compensate the buyer for the excess amount that it is paying for the pool being delivered.13 Pursuant to SIFMA Guidelines, an entity is entitled to make a CPR claim if (i) the allocation or substitution giving rise to the CPR claim occurred after the factor release date,14 following the scheduled contractual settlement date relating to the trade; (ii) the pools involved in the claim meet the criteria for fast paying pools in accordance with SIFMA Guidelines; (iii) the amount of the CPR claim is $10,000 or greater, or, in the

1 Notice, 83 FR, at 39144.
2 Id.
3 Id.
4 Id.
6 The SIFMA Guidelines are trading, clearing and settlement guidelines prepared by SIFMA intended to reflect common industry practices relating to confirming, comparing and settling mortgage-backed securities.
7 Notice, 83 FR, at 39144.
8 The term “factor release date” means, with respect to a pool, the date on which the Federal National Mortgage Association (“Fannie Mae”), the Federal Home Loan Mortgage Corporation (“Freddie Mac”) or the Government National Mortgage Association (“Ginnie Mae”), as applicable, release the “factor” that represents the percentage of the agency’s original balance of the pool that remains outstanding as of such date. Id.

20 Notice, 83 FR, at 39144.
21 A mortgage pool is a collection of mortgage loans or other collateral assembled by an originator or master services as collateral for a mortgage-backed security. Id.


case that an entity is submitting a re-transmittal of a CPR claim, the CPR claim amount is $500 or greater; and (iv) 90 percent of the buyer’s claimable unit has settled.

The proposed rule change would codify FICC’s existing CPR claims process in the MBSD Rules, including adding a provision providing that a Clearing Member’s cash settlement obligations would include the positive or negative amount of any valid CPR claim. FICC states that the proposed MBSD CPR claims process would generally follow the CPR claims process set forth in the SIFMA Guidelines and MBSD’s current CPR claims process, with the following exceptions:

1. Definition of Claimable Unit

The proposed rule change would add to the MBSD Rules two definitions of “claimable unit,” the use of which would depend on the type of transaction. According to SIFMA Guidelines and FICC’s current process, CPR claims are based on a “claimable unit” which defines the pool or group of pools that are included in a particular CPR claim. Also according to SIFMA Guidelines, a claimable unit is based on all pools allocated for a trade between factor release dates that have the same underlying TBA characteristics, such as product, coupon, trade date, settlement date and price.

FICC states that it currently processes CPR claims using a different definition of claimable unit than the SIFMA definition. FICC states that its CPR claims process currently uses a definition of claimable unit based on characteristics of pools after MBSD Pool Netting takes place rather than based on underlying TBA characteristics. The Pool Netting process generally reduces the number of pool settlements by aggregating and matching offsetting allocated pools submitted by Clearing Members to arrive at a single net position per counterparty in a particular pool number. FICC states that if a pool obligation is a result of Pool Netting, FICC is unable to track the pool obligation to an original TBA trade or trades and would be unable to group pool obligations for CPR claims based on TBA characteristics as provided in SIFMA Guidelines.

FICC proposes to use the same definition of claimable unit for CPR claims as SIFMA Guidelines if the pool obligations upon which the CPR claims are based have not been through MBSD Pool Netting. FICC states that this definition would be used for pool allocations or substitutions for pool obligations that have been allocated after the factor release date because pool obligations allocated after the factor release date do not go through the Pool Netting process. As a result, FICC states that it would be able to track the pool obligation to an original TBA trade, which would allow FICC to group the pool obligation with other pool obligations based on TBA characteristics.

FICC proposes to use a different definition of a claimable unit from the SIFMA Guidelines definition for CPR claims based on pool obligations that are a result of Pool Netting. FICC proposes to define a claimable unit for such pool obligations based on pool characteristics after Pool Netting, rather than based on the original TBA pool characteristics. FICC states that this definition would be used for substitutions for pool obligations that are a result of Pool Netting because FICC would be unable to track the pool obligation to an original TBA trade and thus unable to group such pool obligation with other pool obligations based on TBA characteristics.

2. Re-Transmittal Threshold

The minimum threshold for a re-transmittal of a CPR claim under SIFMA Guidelines is $500. FICC’s current process provides that the minimum threshold for re-transmittals is $5,000. FICC proposes to use the $500 re-transmittal minimum threshold for allocations (and related substitutions), where the allocations were made after the applicable factor release date, in order to be more consistent with SIFMA Guidelines and established industry practice. Meanwhile, FICC proposes to use a $5,000 re-transmittal threshold for substitutions relating to allocations that were made prior to the factor release date following the contractual settlement date to avoid having to process multiple smaller transactions, which FICC believes would likely be administratively burdensome.

B. Proposed MBSD Rule Changes

To codify the CPR claims process as described above, the proposed rule change would add a description of the CPR claim process in a new Section 10 of MBSD Rule 9, including a defined term for “CPR Claim.” In addition, the proposed rule change would specify the validation process for CPR claims, which, as described above, would codify existing FICC practices relating to CPR claims and provide that the process for CPR claims is consistent with SIFMA Guidelines, in each case, with the exceptions noted above.

Specifically, the proposed rule change would specify that CPR claims submitted would be reviewed by FICC to validate the following: (i) The claimable unit with respect to the CPR claim meets the criteria for fast paying pools as set forth in SIFMA Guidelines; (ii) the CPR claim amount is $10,000 or greater, unless the CPR claim is a re-transmittal of a CPR claim, in which case, (a) if the CPR claim relates to an allocation of a pool effected after the factor release date following the contractual settlement date and/or substitution of related pools, the amount is $500 or greater, or (b) if the CPR claim relates to a substitution of a pool that was allocated prior to the factor release date following the contractual settlement date, the amount is $5,000 or greater; and (iii) 90 percent of the Clearing Member’s claimable unit has settled.

Consistent with FICC’s current CPR claims process, the proposed rule change would also specify that (1) FICC maintains the right to process CPR claims with no minimum denomination, (2) CPR claims may be apportioned to more than one participant, (3) CPR claims may be comprised of both debits and credits, (4) FICC would process all CPR claims on the Class “B” settlement date in the month following the transmittal month, and (5) FICC would notify the Clearing Member that the CPR claim has been rejected if the CPR claim is determined to be invalid.

In addition, that the proposed rule change would specify that FICC shall not guaranty CPR claim payments, and any credit to be received with respect to a CPR claim would be reduced to the extent the corresponding debit in

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1. A re-transmittal of a CPR claim occurs when a party with the pool deliver obligation passes the CPR claim it received to the entities that sent it the pools it used for delivery. Id.
3. Id.
4. Id.
5. Id.
connection with a CPR claim is not paid.\textsuperscript{35}

FICC states that to ensure that Clearing Members understand the potential credits and debits relating to CPR claims, the proposed rule change would add credits and debits relating to CPR claims in Section 7 of MBSD Rule 11 as items for end of day cash balance computations.\textsuperscript{36}

FICC states that to further describe the CPR claims process as set forth above, a cross-reference for the defined term “CPR Claim” and new defined terms “Claimable Unit” and “Factor Release Date” would be added to MBSD Rule 1, which are consistent with existing FICC practices relating to CPR claims and with SIFMA Guidelines, in each case, with the exceptions noted above.\textsuperscript{37}

FICC states that the definitions for Fannie Mae, Freddie Mac, and Ginnie Mae would be corrected in MBSD Rule 1 to be consistent with industry practice and with their usage throughout the MBSD Rules. In addition, the definition of “SIFMA Guidelines” would be clarified by adding a link identifying the location of the SIFMA Guidelines on the SIFMA website.\textsuperscript{38}

II. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act\textsuperscript{40} directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and rules and regulations thereunder applicable to such organization. The Commission believes the proposal is consistent with the Act, specifically Section 17A(b)(3)(F) of the Act and Rule 17Ad–22(e)(23)(i) under the Act, as discussed below.\textsuperscript{41}

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act\textsuperscript{42} requires, inter alia, that the rules of the clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions. As described above, FICC proposes to codify its existing CPR claims process and to specify the validation procedure for CPR claims. First, FICC proposes to specify that CPR claims submitted would be reviewed by FICC to validate

\[ \text{(i) the claimable unit with respect to the CPR claim meets the criteria for fast paying pools as set forth in SIFMA Guidelines; (ii) the CPR claim amount is $10,000 or greater, unless the CPR claim is a re-transmittal of a CPR claim, in which case, (a) if the CPR claim relates to an allocation of a pool effected after the factor release date following the contractual settlement date and/or substitution of related pools, the amount is $500 or greater, or (b) if the CPR claim relates to a substitution of a pool that was allocated prior to the factor release date following the contractual settlement date, the amount is $5,000 or greater; and (iii) 90 percent of the Clearing Member’s claimable unit has settled.}

Consistent with FICC’s current CPR claims process, FICC also proposes to specify that (1) FICC maintains the right to process CPR claims with no minimum denomination, (2) CPR claims may be apportioned to more than one participant, (3) CPR claims may be comprised of both debits and credits, (4) FICC would process all CPR claims on the Class “B” settlement date in the month following the transmittal month, and (5) FICC would notify the Clearing Member that the CPR claim has been rejected if the CPR claim is determined to be invalid.

In addition, FICC proposes to specify that FICC shall not guaranty CPR claim payments, and any credit to be received with respect to a CPR claim would be reduced to the extent the corresponding debit in connection with a CPR claim is not paid.

These proposed changes would codify FICC’s existing processes surrounding CPR claims and make the CPR claims process more consistent with SIFMA Guidelines. The Commission believes that the codification would enable Clearing Members to better understand how CPR claims would be validated and processed through FICC’s facilities and how FICC’s CPR claims process would differ from SIFMA Guidelines with respect to the definition of claimable unit and the re-transmittal minimum threshold, as set forth above. By enabling Clearing Members to better understand the CPR claims process, the proposal is designed to help ensure that CPR claims are submitted and processed correctly and thus promote the prompt and accurate clearance and settlement of such securities transactions.

Additionally, FICC proposes to make several clarifying changes. First, as described above, the proposed rule change would add credits and debits relating to CPR claims in Section 7 of MBSD Rule 11 as items for end of day cash balance computations. In Second, a cross-reference for the defined term “CPR Claim” and new defined terms “Claimable Unit” and “Factor Release Date” would be added to MBSD Rule 1, which are consistent with existing FICC practices relating to CPR claims and with SIFMA Guidelines, in each case, with the exceptions noted above. Third, the proposed rule change would correct the definitions for Fannie Mae, Freddie Mac and Ginnie Mae in MBSD Rule 1 to be consistent with industry practice and with their usage throughout the MBSD Rules. Fourth, FICC proposes to add a description of the CPR claim process in a new Section 10 of MBSD Rule 9, including a defined term for “CPR Claim.” Finally, the definition of “SIFMA Guidelines” would be clarified by adding a link identifying the location of the SIFMA Guidelines on the SIFMA website.

By proposing these clarifying changes to the CPR claims rules, the Commission believes that the proposed changes are designed to help Clearing Members better understand and remain compliant with the CPR claims rules to help ensure that CPR claims are submitted and processed correctly, and thus promoting the prompt and accurate clearance and settlement of such securities transactions.

As each of the aforementioned changes are designed to promote the prompt and accurate clearance and settlement of securities transactions, the Commission finds that the proposal is consistent with the requirements of Section 17A(b)(3)(F).

B. Consistency with Rule 17Ad–22(e)(23)(i)

Rule 17Ad–22(e)(23)(i) under the Act requires a covered clearing agency\textsuperscript{43} to establish, implement, maintain and enforce written policies and procedures reasonably designed to provide for publicly disclosing all relevant rules and material procedures.\textsuperscript{44}

As described above, the proposed rule changes would (1) codify FICC’s existing CPR claims process and (2) make clarifications to the existing CPR claims process. The Commission

\[ \text{\begin{itemize}
\item 17 CFR 240.17Ad–22(e)(23)(i).
\end{itemize}\]
believes these proposed changes to codify and clarify FICC’s existing practices in regards to the CPR claims process would assist in publicly disclosing all relevant and material procedures regarding the CPR claims process. Therefore, the Commission finds that the proposal is consistent with Rule 17Ad–22(e)(23)(i) under the Act.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act, in particular the requirements of Section 17A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change SR–FICC–2018–006 be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.

Brent J. Fields,
Secretary.

[FR Doc. 2018–20885 Filed 9–25–18; 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 Relating to Risk Protections

September 20, 2018.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”), 1 and Rule 19b-4 thereunder, notice is hereby given that on September 11, 2018, Nasdaq GEMX, LLC (“GEMX” or “Exchange”) filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend GEMX Rules 100(a)(5) which contains definitions, Rule 711, “Acceptance of Quotes and Orders” and Rule 714, “Automatic Execution of Orders.”

The text of the proposed rule change is available on the Exchange’s website at http://www.nasdagemx.com/, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

GEMX proposes to amend Rule 714, Automatic Execution of Orders, by placing all risk protections within this rule and further creating sections to distinguish order protections, order and quote protections and quote protections. The Exchange believes that providing Members with a single rule with all risk protections will provide an easy reference to the mandatory single leg risk protections on GEMX.

The Exchange is amending Rule 714(b) to rename the caption from “Other Order Protections” to “Other Risk Protections.” The Exchange is amending references to “order protections” to “risk protections” within that rule to more broadly describe the type of protections offered on GEMX. Finally, the Exchange is relocating rule text from Rule 714(c) to the end of proposed Rule 714(b), which states, “In the event of unusual market conditions and in the interest of a fair and orderly market, the Exchange may temporarily establish the levels at which the order protections contained in this paragraph are triggered as necessary and appropriate.” The non-substantive rule changes are intended to bring greater clarity to the rule.

The Exchange proposes to add the following to proposed Rule 714(b)(1). “The following are order risk protections on GEMX.” The Exchange proposes to list all order protections within Rule 714(b)(1). The Exchange proposes to relocate Limit Order Price Protection from Rule 714(b)(2) to proposed Rule 714(b)(1)(A). The Exchange also proposes to add a new sentence to the end of proposed Rule 714(b)(1)(A) which provides, “Limit Order Price Protection shall not apply to the Opening Process or during a trading halt.”

The Exchange is adding this sentence, which was not contained in the initial rule change, to make clear the limitations as to when this protection is available on GEMX. The Exchange notes the Limit Order Price Protection rejects orders to buy (sell) as the greater of the Exchange’s best offer (bid) plus (minus) either an absolute dollar or a percentage. The Exchange notes that the bid or offer is not established until after an option series options for trading. Applying this protection during the Opening Process is not necessary as the quote width allowance is tighter during the Opening Process. With respect to trading halts, Opening Process procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for a trading halt and the same restrictive boundaries would apply. This sentence memorializes the Exchange’s current practice. The Exchange believes that this rule text will bring greater clarity to the Limit Order Price Protection functionality.

The Exchange proposes to relocate and re-number Market Order Spread Protection from Rule 711(c) to proposed Rule 714(b)(1)(B). The Exchange also proposes to add a sentence which provides, “Market Order Spread Protection shall not apply to the Opening Process or during a trading halt.”

The Exchange believes that the Market Order Spread Protection is unnecessary during the Opening Process and during a trading halt because protections are in place during the Opening Process to ensure that the best bid and offer displayed on the Exchange are within a reasonable range.

...
Opening Process has more restrictive boundaries than those proposed for the Market Order Spread Protection. With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market requires a bid/ask differential applicable to the best bid and offer from all Valid Width Quotes defined in a table6 to be determined by the Exchange. The Exchange’s requirements during the Opening Process are more restrictive than the proposed initial setting for the Market Order Spread Protection, which is proposed at $5. As provided in Rule 701(d), trading halts are subject to the reopening process as provided for in Rule 701(e). The same protections noted for the Opening Process above will apply for trading halts. The Exchange believes that the Market Order Spread Protection is unnecessary during the Opening Process and during a trading halt because other protections are in place to ensure that the best bid and offer displayed on the Exchange are within a reasonable range. The Exchange is adding this sentence to make clear the limitations as to when this protection is available on GEMX. The Exchange believes that this rule text will bring greater clarity to the Market Order Spread Protection functionality.

The Exchange is also memorializing a sentence which was contained in the filing which adopted Market Order Spread Protection. The Exchange noted in the adopting filing that the Exchange may establish differences other than the referenced threshold for one or more series or classes of options.8 At this time, the Exchange proposes to memorialize this capability within Rule 714(b)(1)(B) by stating, “The Exchange may establish different thresholds for one or more series or classes of options.” The Exchange believes that adding this provision to the rule will add transparency to the Exchange’s capability to establish different thresholds per options series or class.

The Exchange proposes to relocate Size Limitation from Rule 714(b)(3) to proposed Rule 714(b)(1)(C) without any amendments. The Exchange proposes to add the following to proposed Rule 714(b)(2). “The following are order and quote risk protections on GEMX:” The Exchange proposes to list all order and quote protections within Rule 714(b)(2). The Exchange proposes to re-letter Acceptable Trade Range from Rule 714(b)(1) to proposed Rule 714(b)(2)(A).

The Exchange proposes to relocate Market Wide Risk Protection from Rule 714(d) to proposed Rule 714(b)(1)(D). The Exchange is only amending cross references within this rule to reflect the new location of this text.

The Exchange proposes new rule text at Rule 714(b)(3) which provides, “The following are Market Maker risk protections on GEMX:” The Exchange proposes to list all Market Maker protections within Rule 714(b)(3). The Exchange proposes to relocate Anti-Internalization from Supplementary Material 03 to Rule 804 to proposed Rule 714(b)(3)(A). The Exchange proposes to replace the words “Market participant identifier” with “Market Maker identifier.” The Exchange also proposes to replace the words “Exchange account identifier” with “account number.” 9 The Exchange believes these modifications will bring more clarity to the functionality. The Exchange is removing the words “Notwithstanding Rule 804(d)(1) above” which refer to the firm quote.10 The Exchange notes that the submission of bids and offers must be firm notwithstanding any protection offered by the Exchange, not just Anti-Internalization. The Exchange does not believe it is necessary to specifically cite this caveat for this order protections. The Exchange also proposes to capitalize the defined term Market Maker in this sentence.

The Exchange proposes to relocate Automated Quotation Adjustments from Rule 804(g) to proposed Rule 714(b)(3)(B). Rule 804(g) will be reserved. The Exchange is amending references in the rule to reflect the new placement within Rule 714 and replacing the words “Exchange’s system (“System”)” with the defined term System.11 Finally, the term “member” was capitalized because it is a defined term. The Exchange is also making clear within Rule 715(b)(3)(E)(vi) that Market Makers must request the Exchange enable re-entry by contacting the Exchange’s Operations Department.

Finally, the Exchange proposes to amend the definition of badge within Rule 100(a)(5) to state that a badge is an account number, which may contain letters and/or numbers, assigned to Market Makers. The Exchange may from time to time modify the manner in which a badge is expressed systemically. This proposed language allows for latitude in establishing badges within the System.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,12 in general, and furthers the objectives of Section 6(b)(5) of the Act,13 in particular, in that 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 grouping the various risk protections into a single rule for ease of reference and adding headers to the rule to make clear whether the risk protection is an order protection, order or quote protection or a protection applicable to Market Makers. The Exchange believes the reorganization of the existing rule and relocation of various rules into Rule 714 is a non-substantive rule change. The Exchange believes that this rule change is consistent with the protection of investors and the public interest because it will bring greater transparency to the protections offered on GEMX.

The Exchange’s proposal to not apply the Limit Order Price Protection during the Opening Process is consistent with the Act because the Exchange rejects orders to buy (sell) as the greater of the Exchange’s best offer (bid) plus (minus) either an absolute dollar or a percentage. The Exchange notes that the bid or offer is not established until after an option series options for trading. Applying this protection during the Opening Process is not necessary as the quote with allowance is tightened during the Opening Period. The Exchange proposes to relocate these options to Rule 100(a)(64).

The Exchange proposes to amend the definition of System within Rule 100(a)(6) by stating that a System is a system operated by the Exchange that receives and disseminates quotes, executes orders and reports transactions. The Exchange proposes to relocate these options to Rule 100(a)(6).
Process.14 With respect to trading halts, Opening Process procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for a trading halt and the same restrictive boundaries would apply.

The Exchange’s proposal to not apply the Market Order Spread Protection during the Opening Process is consistent with the Act because protections exist during the Opening Process to ensure that the best bid and offer displayed on the Exchange are within a reasonable range. The Exchange’s Opening Process Rule 70116 and the reopening process after a trading halt 17 both contain more restrictive boundaries than those proposed or the Market Order Spread Protection. With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market requires a bid/ask differential applicable to the best bid and offer from all Valid Width Quotes defined in a table to be determined by the Exchange. The Exchange’s requirements during the Opening Process are more restrictive than the proposed initial setting for the Market Order Spread Protection, which is set at $5. The same protections noted for the Opening Process above will apply for trading halts. The Exchange believes that the Market Order Spread Protection is unnecessary during the Opening Process and during a trading halt because other protections are in place to ensure that the best bid and offer displayed on the Exchange are within a reasonable range.

Memorializing the ability of the Exchange to establish different Market Order Spread Protection thresholds per options series or class will also bring greater clarity to the rule. Today, the Exchange has this ability, it is simply adding that text to the rule. Utilizing defined terms within the Rulebook will also bring clarity to the rules. The Exchange also believes using more discrete language within the Anti-

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 proposal does not impose an intra-market burden on competition with respect to the reorganization and relocation of the various rules into Rule 714 because the various risk protections are mandatory and will continue to apply uniformly to all market participants. The Exchange also believes that the addition of specific limitations to both the Limit Order Price Protection and Market Order Spread Protection rules will provide market participants with greater information as to when these protections will apply. These limitations apply uniformly to all market participants. The remainder of the rule changes are intended to bring greater transparency to the current operation Exchange’s rules.

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) of the Act 19 and Rule 19b–4(f)(6) thereunder.20 A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)22 permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange argues that waiver of the operative delay would allow the Exchange to immediately incorporate all risk protections into Rule 714 and bring greater transparency to the risk protections offered on the Exchange. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.23

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 change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments
• Use the Commission’s internet comment form (http://www.sec.gov/rules/sro.shtml); or
• Send an email to rule-comments@sec.gov. Please include File Number SR–GEMX–2018–32 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–2018–32. This file number should be included on the

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14 With respect to the Opening Process, a Quality Opening Market is required. A Quality Opening Market a bid/ask differential applicable to the best bid and offer from all Valid Width Quotes defined in a table to be determined by the Exchange and published on the Exchange’s website. See GEMX Rule 701(a)(7).
15 See GEMX Rule 701(d).
16 See note 14 above.
17 With respect to trading halts, Opening Process procedures will be used to reopen an option series after a trading halt, therefore, the same protections noted for the Opening Process will apply for a trading halt and the same restrictive boundaries would apply. See GEMX Rule 701(d).
18 The table is located at: https://business.nasdaq.com/media/GEMXsystemSetting_tcm5044–41251.pdf.
20 17 CFR 240.19b–4(f)(6). As required under Rule 19b–4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.
23 For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).
Delegations of Authority: Delegation of Authority No. 12–G (Revision 1), Amendment 1

AGENCY: U.S. Small Business Administration.

ACTION: Notice of Amendment to Delegation of Authority.

SUMMARY: This document provides the public notice of an amendment to Delegation of Authority No. 12–G (Revision 1) (79 FR 56842, September 23, 2014) (the “Delegation”), which delegated authority for lender oversight and enforcement activities by the Administrator of the Small Business Administration (“SBA”) to the Director, Office of Credit Risk Management (“OCCRM”), the Lender Oversight Committee (“LOC”), and the Associate Administrator for Capital Access (“CA/CA”). By this amendment (this “Amendment”), the Administrator is delegating additional lender oversight authority to the OCCRM and revising the membership of the LOC consistent with new requirements in The Small Business 7(a) Lending Oversight Reform Act of 2018 (June 21, 2018). This Amendment to the Delegation includes the authority of the OCCRM to participate in the review and approval of initial applications by 7(a) Lenders and Certified Development Companies (“CDCs”) for delegated lending authorities. This Amendment also provides that the OCCRM consult with the Director, Office of Financial Assistance (“OFA”) on Community Advantage Pilot Program (“Community Advantage”) authority. Finally, this Amendment implements the new statutory provisions revising LOC membership and voting authority.

FOR FURTHER INFORMATION CONTACT: Bethany J. Shana, Office of Credit Risk Management, U.S. Small Business Administration, 409 3rd Street SW, Washington, DC 20416, telephone number: (202) 205–402 and electronic mail: bethany.shana@sba.gov.

SUPPLEMENTARY INFORMATION: This document provides the public notice of an amendment to the Administrator’s Delegation of Authority with respect to SBA’s lender oversight and enforcement activities. Specifically, this Amendment delegates to the OCCRM the authority to concur or non-concur on recommendations to the OFA on initial applications for delegated lending authority, which include initial applications by 7(a) Lenders for participation in the Preferred Lenders Program (“PLP”), SBA Express Program, and Export Express Program, and initial applications by CDCs for participation in the Accredited Lenders Program (“ALP”), including Priority status—a prerequisite to ALP authority, and Premier Certified Lenders Program (“PCLP”). This Amendment further delegates to the OCCRM the authority to concur or non-concur on recommendations to the Director, Office of Financial Program Operations on initial applications for Authorized CDC Liquidator authority (“ACL”) and other types of delegated lending authority established in the future, unless otherwise provided. In addition, this Amendment requires the OCCRM to consult with the OFA on Community Advantage participation determinations. The preceding changes will allow the OCCRM and OFA to provide input into determinations on initial applications for delegated lending authority and Community Advantage participation, respectively.

This Amendment also implements membership and voting requirements for the LOC set forth in Public Law 115–189, the Small Business 7(a) Lending Oversight Reform Act of 2018 (June 21, 2018). Public Law 115–189 added Section 46(b) to the Small Business Act, requiring that the LOC consist of at least eight members. Three members of the LOC are to be voting members, two of whom must be career appointees in the Senior Executive Service. The remaining members are to be nonvoting members who serve in an advisory capacity on the LOC. This Amendment designates the following SBA employees as the voting members of the LOC: (i) The Chief Financial Officer, a Senior Executive Service career appointee; (ii) the Associate Administrator for Capital Access, a Senior Executive Service non-career appointee; and (iii) the Associate Administrator for Disaster Assistance, a Senior Executive Service career appointee. The Chief Financial Officer will serve as the LOC Chairperson. This Amendment also updates the Administrator’s designation of nonvoting advisory members as set forth below.

This Amendment replaces (i) Section I.A.1 of the Delegation in its entirety, which covers delegations of authority to the OCCRM for delegated lender authority and Community Advantage participation, and (ii) Section I.B.6 of the Delegation in its entirety, which covers LOC membership and voting, as set forth below. All other sections of the Delegation are unchanged and continue in effect. Delegation of Authority No. 12–G (Revision 1), Amendment 1 reads as follows:

Delegation of Authority No. 12–G (Revision 1), is amended by revising sections I.A.1. and I.B.6. to read as follows:


a. Initial applications for delegated lending authority. To concur or non-concur on recommendations to the Director, Office of Financial Assistance (OFA) (and, with respect to
set forth in this delegation is the final OCRM's determination on the renewals delegated authority request. The D/OCRM may also approve or decline the additional renewal request, the D/OCRM may also request. If an SBA Lender requests D/OCRM may approve or decline the renewal request is declined or an SBA authority and final agency decision. If a loans on the Secondary Market.

renewal of: i. PLP authority, including PLP–EWCP authority; ii. SBA Express authority; iii. Export Express authority; iv. ALP authority; v. PCLP authority; and vi. Other delegated lending authority. c. Community Advantage Pilot Program participation. i) To approve or decline, in consultation with the D/FA, a lender’s application for participation in the Community Advantage Pilot Program (Community Advantage), including delegated lending authority and/or the authority to sell Community Advantage loans on the Secondary Market. (ii) To approve or decline, in consultation with the D/FA, the renewal of a lender’s participation in Community Advantage, including delegated lending authority and/or the authority to sell Community Advantage loans on the Secondary Market. d. Reapplications, additional authority and final agency decision. If a renewal request is declined or an SBA Lender’s delegated authority expires and the SBA Lender later reapplications, the D/OCRM may approve or decline the request. If an SBA Lender requests additional delegated authority with its renewal request, the D/OCRM may also approve or decline the additional delegated authority request. The D/OCRM’s determination on the renewals and Community Advantage authority as set forth in this delegation is the final Agency decision.

B. To the Lender Oversight Committee: * * * * * 6. The Lender Oversight Committee will consist of SBA’s: (i) Chief Financial Officer (CFO) (Chairperson and voting member); (ii) Associate Administrator for Capital Access (AA/CA) (voting member); (iii) Associate Administrator for Disaster Assistance (AA/DA) (voting member); (iv) D/FA (non-voting, recommending advisory member); (v) D/FA (non-voting advisory member); (vi) Director, Office of Financial Program Operations (non-voting advisory member); (vii) Associate Administrator, Office of Field Operations (non-voting advisory member); and (viii) General Counsel (non-voting advisory member).


Dated: September 18, 2018.

Linda E. McMahon, Administrator.

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15692 and #15693; Kansas Disaster Number KS–00119]

Administrative Declaration of a Disaster for the State of Kansas

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Kansas dated 09/14/2018. Incident: Flash Flooding, Flooding and Severe Storms. Incident Period: 09/01/2018 through 09/03/2018.

DATES: Issued on 09/14/2018.

Physical Loan Application Deadline Date: 11/13/2018.

Economic Injury (EIDL) Loan Application Deadline Date: 06/14/2019.

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 Administrator’s disaster declaration, 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: Riley.


The Interest Rates are:

For Physical Damage:

Homeowners with Credit Available Elsewhere ...................... 4.000

Homeowners without Credit Available Elsewhere ................. 7.350

Businesses without Credit Available Elsewhere .................. 2.500

Businesses with Credit Available Elsewhere ....................... 2.000

Non-Profit Organizations with Credit Available Elsewhere ... 3.675

Non-Profit Organizations without Credit Available Elsewhere ... 2.500

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 15692 6 and for economic injury is 15693 0.

The State which received an EIDL Declaration # is Kansas.

(Catalog of Federal Domestic Assistance Number 59008)

Dated: September 14, 2018.

Linda E. McMahon, Administrator.

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Revised Approval of Information Collection Certification Procedures for Products and Parts

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB)
approval to renew a previously approved information collection. Applicable federal regulations prescribe certification standards for aircraft, aircraft engines, propellers and parts. The information collected is used to determine compliance and applicant eligibility. The respondents are aircraft parts designers, manufacturers, and aircraft owners.

DATES: Written comments should be submitted by November 26, 2018.

ADDRESSES: Send comments to the FAA at the following address: Barbara Hall, Federal Aviation Administration, ASP–110, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA’s performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB’s clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Barbara Hall by email at: Barbara.L.Hall@faa.gov; phone: 940–594–5913.

SUPPLEMENTARY INFORMATION: OMB Control Number: 2120–0018.

Title: Certification Procedures for Products and Parts.

Form Numbers: FAA Forms 8110–12, 8130–1, 8130–6, 8130–9, 8130–12.

Type of Review: Renewal with change.

Background: 14 CFR part 21 prescribes certification standards for aircraft, aircraft engines, propellers and parts. The information collected is used to determine compliance and applicant eligibility. FAA Airworthiness inspectors, designated inspectors, engineers, and designated engineers review the required data submittals to determine that aviation products and articles and their manufacturing facilities comply with the applicable requirements, and that the products and articles have no unsafe features.

This request is to make changes to FAA Form 8130–6, APPLICATION FOR U.S. AIRWORTHINESS CERTIFICATE to include new entries for the SPECIAL AIRWORTHINESS CERTIFICATE Categories, Section II. CERTIFICATION REQUESTED, BLOCK 4: EXPERIMENTAL UNMANNED AIRCRAFT. The new categories to be added to the form will be annotated by blocks 9D—SHOW COMPLIANCE WITH CFR and 9E—EXHIBITION. The FAA continues to move toward the electronic collection of data for some of its information collections and electronic signatures. As such, the FAA is working to develop the ASKME Segment 2 Airworthiness Application (AWC) that would allow the electronic collection of the specific information requested in these forms. Testing for this effort is underway with scheduled field implementation targeted for early 2019.

Respondents: Approximately 16,773 aircraft parts designers, manufacturers, and aircraft owners.

Frequency: On occasion.

Estimated Average Burden per Response: .55 hours.

Estimated Total Annual Burden: 12,916.6 hours.

Issued in Washington, DC, on September 18, 2018.

Barbara L. Hall, FAA Information Collection Clearance Officer, Performance, Policy, and Records Management Branch, ASP–110.

[FR Doc. 2018–20871 Filed 9–25–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Disclosure of Seat Dimensions To Facilitate the Use of Child Safety Seats on Airplanes During Passenger-Carrying Operations

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Federal Aviation Administration (FAA) invites public comments about our intention to request Office of Management and Budget (OMB) approval to renew an information collection. The collection involves each passenger carrying air carrier operating under part 121 of title 14, Code of Federal Regulations, to post on the internet website of the air carrier the maximum dimensions of a child safety seat that can be used on each aircraft operated by the air carrier to enable passengers to determine which child safety seats can be used on those aircraft. As a result, the FAA amended 14 CFR 121.311, which requires passenger carrying air carriers to make available on their websites the width of the widest passenger seat in each class of service for each make, model and series of airplane used in passenger-carrying operations (80 FR 58575). Section 412 of Public Law 112–95 requires that all air carriers provide this required information on their internet websites. The vast majority of this burden occurred on a one-time basis as air carriers initially provided information on their websites in order to comply with the regulation. After initial implementation, the only time air carriers need to update their websites after initial implementation is when a
new airplane make, model, or series is introduced to an air carrier’s fleet, or when an air carrier replaces the widest or narrowest seats installed on an existing airplane make, model, or series with wider or narrower seats. The purpose of this collection is to facilitate the use of child restraint systems onboard airplanes by providing greater information to caregivers to help them determine whether a particular child restraint system will fit in an airplane seat.

Respondents: 50 part 121 air carriers.

Frequency: On occasion.

Estimated Average Burden per Response: 7 hours.

Estimated Total Annual Burden: 350 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for the FAA’s performance; (b) the accuracy of the estimated burden; (c) ways for the FAA to enhance the quality, utility, and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB’s clearance of this information request.

Issued in Washington, DC, on September 8, 2018.

Barbara L. Hall,
FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, ASP–110.

[FR Doc. 2018–20872 Filed 9–25–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent of Waiver With Respect to Land

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA is considering a proposal to change 55.4 acres of airport land from aeronautical use to non-aeronautical use and to authorize the sale of airport property Rantoul National Aviation Center-Frank Elliott Field, Rantoul, Illinois. The aforementioned land is not needed for aeronautical use. The parcels are located east of Pacesetter Drive and Galaxy Drive on Rantoul National Aviation Center-Frank Elliott Field. The Village of Rantoul has determined that the parcels are no longer needed for the direct operations of the airport.

DATES: Comments must be received on or before October 26, 2018.

ADDRESSES: Documents are available for review by appointment at the FAA Chicago Airports District Office, Gary Wilson, Program Manager, 2300 East Devon Avenue, Des Plaines, IL 60018, Telephone: (847) 294–7631/Fax: (847) 294–7046 and Eric Vences, Rantoul National Aviation Center-Elliott Field, 6 Aviation Center Drive (217) 892–6896. Written comments on the Sponsor’s request must be delivered or mailed to: Gary Wilson, Program Manager, Federal Aviation Administration, Program Manager, Chicago Airports District Office, 2300 E Devon Avenue, Des Plaines, IL 60018. Telephone Number: (847) 294–7631/FAX Number: (847) 294–7631.

FOR FURTHER INFORMATION CONTACT: Gary Wilson, Program Manager, Federal Aviation Administration, Chicago Airports District Office, 2300 E Devon Avenue, Des Plaines, IL 60018. Telephone Number: (847) 294–7631/FAX Number: (847) 294–7046.

SUPPLEMENTARY INFORMATION: In accordance with section 47107(h) of Title 49, United States Code, this notice is required to be published in the Federal Register 30 days before modifying the land-use assurance that requires the property to be used for an aeronautical purpose. The parcels were transferred to the Village of Rantoul in quitclaim deeds dated July 12, 2007, July 23, 2017, July 9, 2018 and August 17, 2018 under and pursuant to the powers and authority contained in the Base Closure and Realignment Act of 1988 and 1990, as amended. The transfer documents included the National Emergency Use Provision (NEUP). The Village of Rantoul signed a purchase agreement for the parcels which exceeds their fair market value. The revenue received from the sale of this land will be used towards the operation and maintenance of the airport.

The disposition of proceeds from the sale of the airport property will be in accordance with FAA’s Policy and Procedures Concerning the Use of Airport Revenue, published in the Federal Register on February 16, 1999 (64 FR 7696).

This notice announces that the FAA is considering the release of the subject airport property at the Rantoul National Aviation Center-Frank Elliott Field, Rantoul, Illinois from federal land covenants, subject to a reservation for continuing right of flight as well as restrictions on the released property as required in FAA Order 5190.6B section 22.16. Approval does not constitute a commitment by the FAA to financially assist in the disposal of the subject airport property nor a determination of eligibility for grant-in-aid funding from the FAA. FAA has requested the Department of Defense to concur in the release of the National Emergency Use Provision (NEUP) from the subject parcels.

Parcel A3a

A tract of land being a part of Section 2, Township 21 North, Range 9 East of the Third Principal Meridian, Champaign County, Illinois, described as follows: Beginning at a Rantoul Brass Monument found stamped “Rantoul Survey Monument IMLS 2280” found at intersection of the Southeasterly Right-of-Way Line of Galaxy Drive and the Northeasterly Right-of-Way line of Pacesetter Drive, said corner being Designated Point Number 288 and shown as such on Plat of Survey by David P. Phillippe, Illinois Professional Land Surveyor 2591, dated July 9, 2007 and recorded as Document Number 2007R22404 in the Recorder’s Office of Champaign County, Illinois; thence North 44 Degrees 16 Minutes 24 Seconds East along the Southeasterly Right-of-Way Line of said Galaxy Drive, a distance of 756.86 feet to an Iron Pipe Survey Monument Set; thence South 45 Degrees 20 Minutes 30 Seconds East, a distance of 756.43 feet to an Iron Pipe Survey Monument Set; thence South 45 Degrees 20 Minutes 30 Seconds West, a distance of 756.86 feet to an Iron Pipe Survey Monument Set; thence North 45 Degrees 19 Minutes 50 Seconds West, a distance of 757.78 feet to the Point of Beginning, encompassing 13.17 acres, more or less, situated in the Village of Rantoul, Champaign County, Illinois.

Parcel A3b

A tract of land being part of Section 11 and a part of Section 2 Township 21 North, Range 9 East of the Third Principal Meridian, Champaign County, Illinois, described as follows:

Beginning at a Rantoul Brass Monument found stamped “Rantoul Survey Monument IMLS 2280” found at the intersection of the Southeasternly Right-of-Way Line of Galaxy Drive and the Northeasterly Right-of-Way Line of Pacesetter Drive, said corner being Designated Point Number 288 and shown as such on Plat of Survey by David P. Phillippe, Illinois Professional Land Surveyor 2591, dated July 9, 2007 and recorded as Document Number 2007R22404 in the Recorder’s Office of Champaign County, Illinois; thence North 44 Degrees 16 Minutes 24 Seconds East along the Southeasterly Right-of-Way Line of said Galaxy Drive,
a distance of 756.86 feet to an Iron Pipe Survey Monument Set; thence South 45 Degrees 42 Minutes 05 Seconds East, a distance of 836.43 feet to an Iron Pipe Survey Monument Set; thence South 00 Degrees 32 Minutes 38 Seconds East, a distance of 628.97 feet to an Iron Pipe Survey Monument Set; thence South 44 Degrees 25 Minutes 02 Seconds West, a distance of 407.53 feet to an Iron Pipe Survey Monument Set; thence North 61 Degrees 03 Minutes 57 Seconds West, a distance of 197.21 feet to an Iron Pipe Survey Monument Set; thence North 45 Degrees 31 Minutes 42 Seconds West, a distance of 618.98 feet to an Iron Pipe Survey Monument Set on the Easterly Right-of-Way Line of Pacesetter Drive; thence North 00 Degrees 30 Minutes 33 Seconds West along the Easterly Right of Way of said Pacesetter Drive, a distance of 161.61 feet to an Iron Pipe Survey Monument Set; thence North 44 Degrees 10 Minutes 19 Seconds East, a distance of 789.23 feet to the Point of Beginning, encompassing 16.67 acres, more or less, situated in the Village of Rantoul, Champaign County, Illinois.

A2c–8

A tract of land being part of Section 11 and a part of Section 2, Township 21 North, Range 9 East of the Third Principal Meridian, Champaign County, Illinois, described as follows:

Commencing at a Rantoul Brass Monument found stamped “Rantoul Survey Monument IPLS 2280” found at the intersection of the Southeasterly Right of Way Line of said Pacesetter Drive and the Northeasterly Right-of-Way Line of Pacesetter Drive, said corner being designated Point Number 288 and shown as such on Plat of Survey by David P. Philippe, Illinois Professional Land Surveyor 2591, dated July 9, 2007 and recorded as Document Number 2007R22404 in the Recorder’s Office of Champaign County, Illinois; thence South 45 Degrees 33 Minutes 11 Seconds East along the Northeasterly Right of Way Line of said Pacesetter Drive, a distance of 807.77 feet to a Brass Monument stamped “Rantoul Survey Monument IPLS 2280” found at a bend point in the Right-of-Way of said Pacesetter Drive; thence South 00 Degrees 30 Minutes 33 Seconds East along the Easterly Right-of-Way Line of said Pacesetter Drive, a distance of 235.65 feet to a Brass Monument stamped “Rantoul Survey Monument IPLS 2280” found at a bend point in the Right-of-Way of said Pacesetter Drive; thence South 44 Degrees 27 Minutes 02 Seconds West along the Southeasterly Right of Way Line of said Pacesetter Drive, a distance of 57.81 feet to an Iron Pipe Survey Monument Set at a point of beginning; thence South 45 Degrees 31 Minutes 42 Seconds East, a distance of 596.63 feet to an Iron Pipe Survey Monument Set; thence South 44 Degrees 35 Minutes 13 Seconds West, a distance of 643.44 feet to an Iron Pipe Survey Monument Set; thence around a circular curve concave to the North, having a radius of 100.00 feet, a chord length of 141.13 feet, a chord bearing South 89 Degrees 28 Minutes 04 Seconds West, for an arc length of 156.66 feet to an Iron Pipe Survey Monument Set on the Northeasterly Right-of-Way Line of said Pacesetter Drive; thence North 45 Degrees 30 Minutes 02 Seconds East along the Northeasterly Right-of-Way Line of said Pacesetter Drive a distance of 495.28 feet to an Iron Pipe Survey Monument Set on the Northeasternly Right of Way Line of said Pacesetter Drive; thence North 44 Degrees 39 Minutes 04 Seconds West along the Northeasternly Right-of-Way Line of said Arends Boulevard a distance of 744.31 feet to the point of beginning, encompassing 10.12 acres, more or less, situated in the Village of Rantoul, Champaign County, Illinois.

A1b–4

A tract of land being a part of Section 11, Township 21 North, Range 9 East of the Third Principal Meridian, Champaign County, Illinois, described as follows:

Commencing at a Rantoul Brass Monument found stamped “Rantoul Survey Monument IPLS 2280” found at the intersection of the Southeasterly Right-of-Way Line of Galaxy Drive and the Northeasterly Right-of-Way Line of Pacesetter Drive, said corner being designated point number 288 and shown as such on Plat of Survey by David P. Philippe, Illinois Professional Land Surveyor 2591, dated July 9, 2007 and recorded as Document Number 2007R22404 in the recorder’s office of Champaign County, Illinois; thence North 44 Degrees 16 Minutes 24 Seconds East along the Southeasterly Right-of-Way Line of said Galaxy Drive, a distance of 836 feet to an Iron Pipe Survey Monument Set; thence South 45 Degrees 42 Minutes 05 Seconds East, a distance of 1,305.88 feet to an Iron Pipe Survey Monument Set; thence South 00 Degrees 32 Minutes 38 Seconds East a distance of 695.34 feet to an Iron Pipe Survey Monument Set; thence South 44 Degrees 00 Minutes 02 Seconds West a distance of 836 feet to an Iron Pipe Survey Monument Set; thence South 45 Degrees 38 Minutes 48 Seconds West, a distance of 132 feet to an Iron Pipe Survey Monument Set; thence North 40 Degrees 42 Minutes 38 Seconds East, a distance of 306.46 to an Iron Pipe Survey Monument Set, thence South 45 Degrees
37 Minutes 27 Seconds East, a distance of 131.32 feet to an Iron Pipe Survey Monument set; thence South 44 Degrees 25 Minutes 02 Seconds West, a distance of 306.41 feet to the Point of Beginning, encompassing 0.93 acres, more or less, situated in the Village of Rantoul, Champaign County, Illinois.

A1b–3:1

A tract of land being part of Section 11, Township 21 North, Range 9 East of the third Principal Meridian, Champaign County, Illinois, described as follows:

Commencing at a Rantoul Brass Monument found stamped “Rantoul Survey Monument IPLS 2280” found at the intersection of the Southeasterly Right-of-Way Line of Galaxy Drive and the Northeasterly Right-of-Way Line of Pacesetter Drive, said corner being Designated Point Number 288 and shown as such on Plat of Survey by David P. Phillippe, Illinois Professional Land Surveyor 2591, dated July 9, 2007 and recorded as Document Number 2007R22404 in the recorder’s office of Champaign County, Illinois; thence North 44 Degrees 36 Minutes 24 Seconds east along the Southeasterly Right-of-Way Line of said Galaxy Drive, a distance of 836.86 feet to an Iron Pipe Survey Monument set; thence South 45 Degrees 42 Minutes 05 Seconds East, a distance of 1,351.83 feet to an Iron Pipe Survey Monument set; thence south 60 Degrees 32 Minutes 38 Seconds East, a distance of 605.34 feet to an Iron Pipe Survey Monument set; thence South 44 Degrees 25 Minutes 02 Seconds West, a distance of 1,225.29 feet; thence North 45 Degrees 38 Minutes 48 Seconds West, a distance of 80.00 feet to an Iron Pipe Survey Monument set at a point of beginning; thence continue North 45 Degrees 38 Minutes 48 Seconds West, a distance of 132.22 feet to an Iron Pipe Survey Monument set; thence north 44 Degrees 35 Minutes 13 Seconds East, a distance of 306.46 feet to an Iron Pipe Survey Monument set; thence South 45 Degrees 37 Minutes 27 Seconds East, a distance of 131.32 feet to an Iron Pipe Survey Monument set; thence South 44 Degrees 25 Minutes 02 Seconds West, a distance of 306.41 feet to the point of beginning, encompassing 0.93 acres, more or less, situated in the Village of Rantoul, Champaign County, Illinois.

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Limitation on Claims Against Proposed Public Transportation Projects

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: This notice announces final environmental action taken by the Federal Transit Administration (FTA) for the Metropolitan Transportation Authority New York City Transit (MTA NYC) Canarsie Tunnel Project. The project is subject to limitations on any claims that may challenge this final environmental action.

DATES: By this notice, FTA is advising the public of final agency actions subject to 23 U.S.C. 139(l). A claim seeking judicial review of FTA actions announced herein for the listed public transportation project will be barred unless the claim is filed on or before February 25, 2019.

FOR FURTHER INFORMATION CONTACT: Nancy-Ellen Zusman, Assistant Chief Counsel, Office of Chief Counsel, (312) 353–2577; or Juliet Bochicchio, Environmental Protection Specialist, Office of Environmental Programs, (202) 366–9348. FTA is located at 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 9:00 a.m. to 5:00 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FTA has taken final agency action by issuing a certain approval for the public transportation project listed below. The action on the project, as well as the laws under which such action was taken, is described in the documentation issued in connection with the project to comply with the National Environmental Policy Act (NEPA) and in other documents in the FTA environmental file for the project. Interested parties may contact either the project sponsor or the FTA Regional Office for more information. Contact information for FTA’s Regional Offices may be found at https://www.fta.dot.gov.

This notice applies to all FTA decisions on the listed project as of the issuance date of this notice and all laws under which such actions were taken, including NEPA [42 U.S.C. 4321–4375], Section 4(f) requirements [23 U.S.C. 138, 49 U.S.C. 303], Section 106 of the National Historic Preservation Act [54 U.S.C. 306108], and the Clean Air Act [42 U.S.C. 7401–7671q]. This notice does not, however, alter or extend the limitation period for challenges of project decisions subject to previous notices published in the Federal Register. The project and action that is the subject of this notice follow:

Project name and location: The Alternative Service Plan for the Canarsie Tunnel Project in New York City, New York. Project Sponsor: Metropolitan Transportation Authority New York City Transit. Project description: The project proposes to implement the Alternative Service Plan (ASP), which will provide alternative transit and mobility services to diverted L train riders during the temporary 15-month service suspension of the L train between Brooklyn and Manhattan.

The proposed ASP includes: increased temporary alternative subway service during peak and off-peak hours; new temporary bus routes, including one across 14th Street and four over the Williamsburg Bridge between Brooklyn and Manhattan; new temporary ferry service between Williamsburg, Brooklyn and Stuyvesant Cove, Manhattan; station access and capacity improvements; additional temporary bicycle and pedestrian infrastructure; traffic management strategies, including a temporary busway on 14th Street and the temporary implementation of high-occupancy vehicles with three or more people (HOV3+) on the Williamsburg Bridge. Previously, in 2015, FTA issued a categorical exclusions (CE), for the Canarsie Tunnel Restoration and Resiliency Projects, and in 2016, FTA issued a CE for the Canarsie Tunnel Core Capacity and State of Good Repair Project. The Core Capacity and State of Good Repair Projects included full-tunnel closure and partial-tunnel closure construction options as well as a preliminary concept of MTA NYCT’s alternative service plan for displaced transit riders. Because the proposed alternative service plan is considered a change to the previously approved projects, and is new information not previously reviewed pursuant to NEPA, FTA initiated a Supplemental Environmental Assessment and Section 4(f) Review on the proposed alternative service plan.


Elizabeth S. Riklin, Deputy Associate Administrator for Planning and Environment.

[FR Doc. 2018–20916 Filed 9–25–18; 8:45 am]

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Part II

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Chapter 1
Federal Acquisition Regulations; Final Rules
DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR 2018–0001, Sequence No. 5]

Federal Acquisition Regulation: Federal Acquisition Circular 2005–101; Introduction

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Summary presentation of final rules.

SUMMARY: This document summarizes the Federal Acquisition Regulation (FAR) rules agreed to by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) in this Federal Acquisition Circular (FAC) 2005–101. A companion document, the Small Entity Compliance Guide (SECG), follows this FAC.

DATES: For effective dates see the separate documents, which follow.

RULES LISTED IN FAC 2005–101

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SUPPLEMENTARY INFORMATION: Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these rules, refer to the specific item numbers and subjects set forth in the documents following these item summaries. FAC 2005–101 amends the FAR as follows:

Item I—System for Award Management Registration (FAR Case 2015–003)

This final rule updates the instructions for registration in the System for Award Management (SAM) and corrects an inconsistency involving the timing of registration. In order to correct this inconsistency, the final rule amends FAR 4.1102, 4.1103, and 52.204–7 to require (with some exceptions) offeror registration in SAM prior to submission of an offer.

In addition, the rule requires contracting officers to use the name and physical address from the contractor’s SAM registration for the provided “unique entity identifier”; removes the term “division name” from the FAR text at FAR 4.1102 and clause 52.204–13; and changes the referenced website “acquisition.gov” to “sam.gov” to be consistent with the rest of the FAR. It is not anticipated that the rule will have a significant economic impact on small entities, because the rule only clarifies that offerors must be registered in SAM prior to submission of an offer, which is already necessary in order to submit the required annual representations and certifications with the offer.

Item II—One Dollar Coins (FAR Case 2018–009)

This final rule amends the FAR to implement section 885 of the National Defense Authorization Act for Fiscal Year 2018 (Pub. L. 115–91). Section 885 amends 31 U.S.C. 5112(p) to provide an exception for business operations conducted by an entity under a Government contract from the requirements to accept and dispense $1 coins.

Contracting officers will no longer have to insert FAR clause 52.237–11, Accepting and Dispensing of $1 Coin, into solicitations and contracts. Contractors providing services under Government contracts that involve business operations conducted in U.S. coins and currency will no longer be required to accept $1 coins.

The Regulatory Flexibility Act does not apply to this rule, because this final rule does not constitute a significant FAR revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

Dated: September 17, 2018.

William F. Clark,
Director, Office of Government-wide Acquisition Policy, Office of Government-wide Policy.

Federal Acquisition Circular (FAC) 2005–101 is issued under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator for the National Aeronautics and Space Administration. Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 2005–101 is effective September 26, 2018 except for items I and II, which are effective October 26, 2018.

Dated: September 18, 2018.

Linda W. Neilson,
Director, Defense Acquisition Regulations System.

Dated: September 18, 2018.

Jeffrey A. Koses,
Senior Procurement Executive/Deputy CAO, Office of Acquisition Policy, U.S. General Services Administration.

Dated: September 18, 2018.

William G. Roets, II,
Acting Assistant Administrator, Office of Procurement National Aeronautics and Space Administration.

[FR Doc. 2018–20705 Filed 9–25–18; 8:45 am]

BILLING CODE 6820–EP–P
Changes have been implemented in the "division name" from the FAR text at (now the unique entity identifier). The SAM registration for the provided Data physical address from the contractor's contracting officers to use the name and the proposed rule also required to submission of an offer. In addition, 4.1103, 52.204–7, and 52.212–1(k) to proposed changes to FAR 4.1102, the timing of registration. In order to update the instructions for registration in the Federal Register at proposed rule in the I. Background

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and the National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to update the instructions for registration in the System for Award Management and clarify the timing of registration in the System for Award Management.

DATES: Effective October 26, 2018.

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, at 202–501–1448, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite FAC 2005–101, FAR Case 2015–005.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the Federal Register at 81 FR 31895 on May 20, 2016, to update the instructions for registration in the System for Award Management (SAM) and correct an inconsistency involving the timing of registration. In order to correct this inconsistency, the rule proposed changes to FAR 4.1102, 4.1103, 52.204–7, and 52.212–1(k) to require offeror registration in SAM prior to submission of an offer. In addition, the proposed rule also required contracting officers to use the name and physical address from the contractor’s SAM registration for the provided Data Universal Numbering System (DUNS) (now the unique entity identifier). The proposed rule also removed the term “division name” from the FAR text at FAR 4.1102, clause 52.204–13, and provision 52.212–4. These proposed changes have been implemented in the final rule. Ten respondents submitted comments on the proposed rule.

II. Discussion and Analysis

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. A discussion of the comments and changes to the rule is provided as follows:

A. Summary of Significant Changes in Response to Public Comments

There are no changes from the proposed rule as a result of the public comments received.

B. Analysis of Public Comments

The concerns of many respondents were based on the perception that this rule creates a new requirement for offerors. The Councils emphasize that this rulemaking effort does not create a new requirement for offerors, large or small. The purpose of this rule is to clarify for offerors the required timing of SAM registration, i.e., when should offerors register in SAM. This clarification is necessary because of the following inconsistencies in current FAR language:

• FAR 4.1102 states that prospective contractors shall be registered in SAM (which includes online representations and certifications) prior to contract award (with some exceptions) and FAR clause 52.204–7(b)(1) currently requires the offeror to acknowledge the requirements that a prospective awardee shall be registered in SAM prior to award.

• However, paragraphs (b) and (d) of FAR clause 52.204–8, require that if the provision 52.204–7, System for Award Management, is included in the solicitation, then the offeror shall have completed the annual representations and certifications electronically via the SAM website (which would require registration in SAM). The offeror then verifies, by submission of its offer, that the representations and certifications in SAM are current, accurate, and complete, except for changes identified by the offeror in its offer. This requirement has been in the FAR since 2005, when registering in the legacy Central Contractor Registration (CCR). Along with representations required by FAR 52.212–3 for offers of commercial item acquisitions, these provisions have generally made registration in SAM at the time of offer the de facto requirement, despite the language in FAR 4.1102(a) and 52.204–7 speaking to registration in SAM prior to award.

This final rule corrects the inconsistency. The rule requires all offerors (except as provided at FAR 4.1102) to be registered in SAM at the time of submission of an offer or quotation, consistent with the requirements of FAR clause 52.204–8. Offerors can complete their representations and certifications as part of their SAM registration.

1. Effect on Offers and Competition

Comments: A number of comments were received regarding the effect of this rule on submission of offers.

• One respondent stated that the change could have a potential impact on the prime contractor’s ability to respond in a timely manner to a Request for Technical Proposal (RFTP) on an indefinite-delivery indefinite-quantity (IDIQ) contract where small businesses are used as subcontractors.

• One respondent was concerned that many offerors would not want to register in SAM within the time of offer because they would want to wait until they had the incentive of knowing that they were going to receive the award.

• Another respondent stated that the proposed change requiring offerors to be registered in SAM prior to submitting an offer would increase the possibility of the Government receiving only one bid (the “one bid” issue) in response to a solicitation and would especially impact simplified procurements. Still another respondent stated that the rule will severely limit the number of potential offerors.

• Another respondent was concerned that the reduction of competition would put the Government in a situation where SAM-registered vendors could charge exorbitant prices.

• One respondent commented that the rule would hamper Government efforts to maintain an adequate list of SAM-registered vendors to obtain offers, which could in turn hamper efforts to prevent damage to the Government’s real property loan security while seeking a SAM-registered vendor to perform the work.

• Another respondent stated that requiring SAM registration prior to submitting an offer would potentially restrict a newly formed company, a new division of an existing company, or an existing company that is pursuing its first Government contract from responding to a solicitation. According to the respondent, newly established entities or business units would be disadvantaged, because the proposed rule fails to address how they should respond to certain questions, thereby disadvantaging otherwise qualified...
entities from participating in
competitions until they resolve how to
complete the complicated SAM
registration. The respondent stated that
the proposed change would, in effect,
limit competition to existing SAM-
registered companies, and eliminate
new creative solutions.

• One respondent stated that
restricting business opportunities to
those companies that have completed
SAM registration prior to submitting an
offer would undoubtedly work against the
Better Buying Power initiative
(DoD’s implementation of best practices
to strengthen the Defense Department’s
buying power, improve industry
productivity, and provide an affordable,
value-added military capability to the
Warfighter, including promoting
effective competition and increasing
small business participation).

• Another respondent commented
that the rule would severely limit the
contracting officer’s ability to solicit
offers from vendors who may be willing to
register in SAM, but do not know
about Government requirements until
the Government contract office asks
them for quotes for the new work.

• Finally, a respondent stated that
mandating registration in SAM prior to
proposal submission, in comparison to
current practice of ensuring that parties
are registered prior to receipt of contract
award, may significantly discourage
non-traditional suppliers from
responding to broad agency
announcements and other research and
development (R&D) type solicitation
opportunities of interest.

Response: As stated at the beginning
of section II.B. of this preamble, the
requirement for offerors to be registered in
SAM at time of submission of an offer
is not new. All vendors (unless an
exception cited in FAR 4.1102 applies)
are required to be registered in SAM in
order to complete the annual
representations and certifications when
responding to a Government
solicitation. Therefore, clarifying the
required timing of SAM registration will
not restrict competition and will not
limit the number of offerors.

Although SAM can be used as a
Government source list for
procurements (see FAR 13.103), the
Government also uses other means of
identifying sources using market
research (see FAR part 10).

As stated in FAR clause 52.204–7(e),
offerors that are not registered in SAM
should consider applying for
registration immediately upon issuance of
a solicitation. Offerors or potential
contracting officer assistance in
responding to SAM registration
questions should contact the Federal
Service Desk at https://www.fsd.gov/fsd-
gov/home.do if they need assistance.

2. The SAM Repository

Comment: One respondent stated that,
while they fully supported the
improvements in the SAM registration
system requirements, they strongly
recommended that agencies take time to
address all of the inconsistencies and
ambiguities at once as a piecemeal
approach exacerbates the problems with
SAM and creates additional additional
work in terms of revising processes,
reviewing answers for accuracy, etc.

Some of the concerns expressed by this
respondent related to the inter-
relationship between the various
elements of SAM (i.e., the former CCR
and the Online Representations and
Certifications) the difficulty of
interpreting and understanding new
fields in SAM; and concern about
several specific representations and
certifications required or proposed for
inclusion in SAM.

Response: The concerns of the
respondent are outside the scope of this
case. It is not relevant whether a
question in SAM arose from the CCR or
another system in SAM, since SAM is
now a unified repository. This rule
cannot provide an interpretation of, or
justification for, individual
representations and certifications. These
representations and certifications were
all developed and published in the
Federal Register for public comment
through various individual FAR cases.
This rule corrects the known
inconsistencies relating to the timing of
registration in SAM, not the content of
SAM. As stated in section II.B.1. of this
preamble, offerors needing assistance in
responding to SAM registration
questions should contact the Federal
Service Desk at https://www.fsd.gov/fsd-
gov/home.do.

3. Exception for Joint Ventures

Comment: One respondent expressed
support for the proposed rule; however,
the respondent suggested an exception
for newly formed joint ventures as a
direct result of a procurement
opportunity. The respondent stated that
the Government could either
require proof of submission for SAM
registration as of the date of offer, or
could require proof/verification that
each joint venture entity has an active
SAM registration at the time of proposal
submission.

Response: An exception to SAM
registration requirements to provide for
registration of joint ventures after
submission prior to award is not
practicable, because the contracting
officer needs to review the
annual representations and
certifications to evaluate the offers. Joint
venture agreements should be in place
more than 48–72 hours in advance of
proposal submission, which allows
adequate time for completion of
registration in SAM. It is also not
feasible to rely on the SAM registration of
separate members of the joint
venture, because the Government
collects specific part 19-related joint
venture information in the
representations and certifications
(52.219–1) part of SAM, and the
contracting activity works with Small
Business Administration to validate that
joint ventures meet the requirements of
the small business category which they
have provided in SAM. Offerors that are
not registered in SAM should apply for
registration immediately upon issuance of
the solicitation so that there should be
time for a joint venture or any other
type of business to be registered in SAM
at the time of the submission of an offer.

4. Public Burden

Comment: Several respondents
commented on the public burden that
the proposed rule would impose. One
respondent stated that for larger
companies, the effort to complete a
SAM registration can take many weeks.
This respondent also stated that it had
commented on a proposed FAR rule
covering debarment and suspension,
and had shared in that comment that the
Federal Government had vastly
underestimated the burden associated
with compiling and reporting requisite
information to complete registration in
SAM.

Another respondent stated that this
added requirement may serve to impose
a potential cost on those that otherwise
may have been willing to submit a R&D
idea for funding consideration via long
standing streamlined R&D solicitation
procedures.

Response: As previously stated, this
rule does not impose a new requirement
and is therefore not an impediment for
businesses, because registration in SAM
at time of offer submission is already
required by FAR provision 52.204–6(b)
and (d), if the provision FAR 52.204–7
is in the solicitation.

SAM is the single entry point for the
representations and certifications used in
Federal contracting. This one-time
investment of time of completing the
annual representations and
certifications at time of registration is
less than the time that would be needed
to prepare and submit representations
and certifications manually on paper
and in response to procurement
solicitation. Once a business is
registered in SAM there is an annual
renewal requirement to update the annual representations and certifications, and a requirement for entities to update throughout the year only if an entity’s information has changed. This eliminates the need for potential offerors to complete full representations and certifications on paper multiple times a year when responding to solicitations.

5. Applicability to Subcontractors

Comment: One respondent recommended that the rule clarify that the prime and any key subcontractors are required to be registered upon proposal submission, but that lesser subcontractors or consultants are only required to be registered prior to receipt of a subaward.

Response: Subcontractors or consultants to prime contractors are not required to be registered in SAM.

6. Impact on Small Businesses

See the analysis of public comments on the initial regulatory flexibility analysis in section VI. of this preamble.

IV. OTHER CHANGES FROM THE PROPOSED RULE

A. Baseline

There have been many FAR baseline changes since publication of the proposed rule in May 2016, due to publication of Federal Acquisition Circulators 2005–89 through the present one. In particular, the issuance of the final rule under FAR Case 2015–022, Unique Identification of Entities Receiving Federal Awards, published in FAC 2005–91 on September 30, 2016 (81 FR 67736), changed the term “DUNS number” to “unique entity identifier”.

B. Exemptions at FAR 4.1102 and 18.102

The exemption at FAR 4.1102(a)(5) is an inaccurate rewording of the exemption at FAR 6.302–2, which addresses needs of unusual and compelling urgency. FAR 4.1102(a)(5) and 18.102(a)(1) have been reworded to accurately reflect this exception to include “urgency”. In addition FAR 18.102(a) has been corrected to indicate that 4.1102 exempts contractors from the requirements to be registered at time of submission of offers or quotations. However, 4.1103(b) requires subsequent registration for those offers exempted on the basis of 6.302–2. FAR 18.102 has also been amended to include the exemptions for contracts awarded by contracting officers deployed in certain difficult situations.

C. Other Changes From the Proposed Rule

1. Use and Content of 52.204–7 and 52.204–13

The final rule changes the structure and presentation of the requirements of FAR provisions 52.204–7, System for Award Management, and FAR clause 52.204–13, System for Award Management Maintenance, as well as the means of inclusion of those requirements in solicitations and contracts for the acquisition of commercial items. There were several structural and technical issues that required resolution, without any change in the stated policies of the proposed rule.

a. Prescription for use of 52.204–7 and 52.204–13 and the associated requirements for acquisitions of commercial items. FAR 4.1105(a) requires use of the provision at FAR 52.204–7 in all solicitations unless an exception at FAR 4.1102(a) applies. The provision is used with its Alternate I if the solicitation is for a contract to support needs of unusual and compelling urgency in accordance with FAR 4.1102(a)(5), the exception for contracts to support needs of unusual and compelling urgency in accordance with 6.302–2 (see section IIC.2. of this preamble). Likewise, FAR 4.1105(b) requires use of the clause at FAR 52.204–13 in solicitations that contain the provision at 52.204–7, and resulting contracts (i.e., it will not be used if an exception at FAR 4.1102 applies). However, when this provision and clause are incorporated in paragraph (k) of FAR provision 52.212–1, Instruction to Offerors—Commercial Items; and paragraph (t) of FAR clause 52.212–4, Contract terms and Conditions—Commercial Items, the exceptions must be applied by an addendum to the solicitation and resultant contract, inserted by the contracting officer to exclude applicability of paragraphs (k) and (t), respectively. There are no other paragraphs in 52.212–1 and 52.212–4 that rely on an addendum by the contracting officer to establish inapplicability of the entire paragraph. Nor is there an instruction in the clause prescription alerting the contracting officer to the requirement to include such an addendum. There is high risk that the addendum will not be consistently inserted as required.

Furthermore, with regard to implementation of the equivalent of Alternate I in solicitations for the acquisition of commercial items, the current FAR does not specifically address how to implement Alternate I, bulk deactivating the addendum to the contract to specify the conditions applicable if the contract is in support of needs of unusual or compelling urgency. The proposed rule just inserted the terms “except in instances of urgency,” apparently leaving it to the contractor to determine, and not providing the process to be applied if there are instances of urgency (which is not the same as the terminology at 4.1102(a)(5)) or 6.302–2.

The final rule resolves these issues by removing paragraph (k) from FAR 52.212–1 and paragraph (t) from FAR 52.212–4, and clearly prescribes at 12.301(d) the use of the correct provision or clause at 12.301(d) by referencing the prescriptions at 4.1105(a) and (b) for appropriate use of FAR 52.204–7 (including use with its Alternate I) and FAR 52.204–13.

b. Text of 52.204–7, its Alternate I, and 52.204–13. The text of 52.204–7 included various acknowledgements, which became more awkward when requiring the offeror to acknowledge that the offeror is registered in SAM at time of submission of the offer. These acknowledgements were inconsistent with the location of the provisions in 52.212–1, which is supposed to be instructions to the offeror. The acknowledgements have been replaced with instructions to the offeror, relating to preaward requirements. The postaward requirements have been moved to the FAR clause 52.204–13. There were some errors made in the proposed changes to Alternate I, which is applicable in the circumstances where registration in SAM may be delayed until after award due to urgency. Therefore, if Alternate I is included by the contracting officer in the solicitation, it is not required to be registered in SAM at time of submission of the offer. The only requirement prior to award is that the offeror complete the registration as soon as possible. If registration has not yet occurred at time of award, the offeror is directed to the postaward requirements, which have been moved to the clause 52.204–13.

4. Active in SAM

The language at FAR 4.1103(a)(1) has been changed to specify that offerors must have status designation of “active” in SAM at the time of offer or quotation submission, to distinguish active from inactive registrants in SAM. The “active” state is the normal state for the contractor account. In this state, contractors can log in to SAM and perform all necessary functions. Contractor accounts become inactive either after an extensive period of user inactivity, or if the contractor chooses to voluntarily deactivate the account. To prevent the account from becoming inactive, contractors should log in to
SAM at least once every 13 months (395 days).

5. SAM Website and Terminology
   The final rule changes the referenced website “acquisition.gov” to “sam.gov” to be consistent with the rest of the FAR. “Database” is also removed from “SAM” for consistency throughout.

6. “Offeror” vs. “Prospective Contractor”

   Previously, we noted that the prospective contractor had to register in SAM prior to contract award; not all prospective contractors are required to be registered. Only the offeror/quoter is required to be registered in SAM at time of submission of the offer.

7. Exclusions
   The final rule amends 9.405, 17.207, and 22.1025 to match the terminology proposed at 9.404 with regard to exclusions in SAM.

8. Miscellaneous Edits
   The final rule contains other miscellaneous edits relating to word usage (e.g., “must” vs. “shall” and “quote” vs. “quotation”), punctuation, and capitalization.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold and for Commercial Items, Including Commercially Available Off-the-Shelf Items

   This rule is not statutory and is not subject to 41 U.S.C. 1905 through 1907. This rule clarifies the timing of existing SAM registration requirements. It does not impact the applicability at or below the simplified acquisition threshold or applicability to commercial items. The affected clauses are FAR 52.204–7, System for Award Management; FAR 52.204–8, Annual Representations and Certifications; FAR 52.204–13, System for Award Management Maintenance; FAR 52.212–1, Instructions to Offerors—Commercial Items; FAR 52.212–4, Contract Terms and Conditions—Commercial Items; and 52.212–5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items.

IV. Executive Orders 12866 and 13563

   Executive Orders (E.O.s) 12866 and 13563 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, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

   This rule is not subject to the requirements of E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

   DoD, GSA, and NASA have prepared a Final Regulatory Flexibility Analysis (FRFA) consistent with the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. The FRFA is summarized as follows:

   This rule amends the FAR to update the instructions for System for Award Management (SAM) registration and to clarify the required timing of SAM registration. The objective of the rule is to clarify that the offeror must be registered in SAM at the time of offer submission in order to complete the required annual representations and certifications.

   Comments: Several respondents submitted public comments in response to the initial regulatory flexibility analysis with regard to the impact the rule would have on small businesses. A discussion of the comments is provided as follows:

   According to the respondents, the requirement to be registered in SAM at time of offer submission would—
   • Further restrict competition among small businesses;
   • Discriminate against the small business owner;
   • Effectively shut out small businesses from submitting offers as they generally are not registered in SAM;
   • Slow the procurement processes and not give fair opportunity to all small businesses; and
   • Place an undue burden on small businesses, because the window to participate in a solicitation is short, and for a small business there are competing demands for developing an adequate proposal and completing the SAM registration.

   One respondent recommended that small businesses should be allowed extra time to complete their SAM registration, which would promote small business participation.

   Response: The Government notes that most of these respondents were not small entities. The requirement for offerors to be registered in SAM at time of submission of an offer is not new. All vendors (unless an exception cited in FAR 4.1102 applies) are required to be registered in SAM in order to complete the annual representations and certifications when responding to a Government solicitation. Therefore, clarifying the required timing of SAM registration will not restrict competition and will not limit the number of offerors, whether the business is large or small. About 75 percent of the current registrants in SAM meet the small business size code for their primary North American Industry Classification System (NAICS) code, so there is no indication that required registration in SAM creates an unreasonable impediment to small businesses.

   Once a business, including a small business, is registered in SAM, there is an annual renewal requirement to update the annual representations and certifications, and a requirement for entities to update throughout the year only if an entity’s information has changed. This eliminates the need for potential offerors to complete full representations and certifications on paper multiple times a year when responding to multiple solicitations. There were no changes from the proposed rule in response to these comments.

   The final rule applies, with some exceptions, to small businesses that submit offers to the Federal Government for acquisitions that exceed the micro-purchase threshold. Currently, of the 452,310 active registrants in SAM for “all awards,” 338,207 (75 percent) certified to meeting the size standard as small for their primary NAICS code. We estimate that not more than half of those small businesses will submit an offer in a given year.

   The rule contains information collection requirements. OMB has cleared this information collection requirement under OMB Control Number 9000–0159, titled: System for Award Management Registration (SAM). No alternative approaches were identified that would meet the objectives of the rule. This rule requires offerors to be registered in SAM at the time of submission of an offer, which is necessary in order to submit the required representations and certifications electronically with submission of the offer. It is not anticipated that the rule will have a significant economic impact on small entities, because this is already required by FAR 5.204–8. This approach is less burdensome than submitting annual representations and certifications manually on paper in response to every solicitation.

   Interested parties may obtain a copy of the FRFA from the Regulatory Secretariat Division. The Regulatory Secretariat Division has submitted a copy of the FRFA to the Chief Counsel for Advocacy of the Small Business Administration.

VII. Paperwork Reduction Act

   The Paperwork Reduction Act (44 U.S.C. Chapter 35) applies. The rule contains information collection requirements. OMB has cleared this information collection requirement under OMB Control Number 9000–0159; “System for Award Management Registration”.

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List of Subjects in 48 CFR Parts 1, 2, 4, 7, 8, 9, 12, 13, 16, 17, 18, 19, 22, 23, 25, 26, 28, 32, 44, and 52

Government procurement.

Dated: September 17, 2018.

William F. Clark,
Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 1, 2, 4, 7, 8, 9, 12, 13, 16, 17, 18, 19, 22, 23, 25, 26, 28, 32, 44, and 52 as set forth below:

1. The authority citation for parts 1, 2, 4, 7, 8, 9, 12, 13, 16, 17, 18, 19, 22, 23, 25, 26, 28, 32, 44, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

1.106 [Amended]
2. Amend section 1.106 by removing from the table the entries for FAR segments “52.212–1(k)” and “52.212–4(i)”.

PART 2—DEFINITIONS OF WORDS AND TERMS

2.101 [Amended]
3. Amend section 2.101 in paragraph (b)(2) revising the defined term “Registered in the System for Award Management (SAM) database” to read “Registered in the System for Award Management (SAM)” and by removing from paragraphs (1) and (2), “the SAM database,” and adding “SAM;” in their places.

PART 4—ADMINISTRATIVE MATTERS

4.605 [Amended]
4. Amend section 4.605 by removing from paragraph (b), in the third sentence, “database”.

4.1100 [Amended]
5. Amend section 4.1100 by removing from the introductory text “database”.

6. Amend section 4.1102 by—
   a. Revising paragraph (a) introductory text;
   b. Removing from paragraph (a)(2) “the SAM database;” and adding “SAM;” in its place;
   c. Revising paragraphs (a)(5) and (6);
   d. Redesignating paragraph (c) as paragraph (d);
   e. Adding a new paragraph (c);
   f. Revising newly redesignated paragraph (d)(1); and
   g. Removing from newly redesignated paragraph (d)(3) “the SAM database” and adding “SAM” in its place.

The revisions and addition reads as follows.

4.1102 Policy.
(a) Offerors and quoters are required to be registered in SAM at the time an offer or quotation is submitted in order to comply with the annual representations and certifications requirements except for—
   * * * * *
(5) Contracts awarded without providing for full and open competition due to unusual or compelling urgency (see 6.302–2);
(6) Contract actions at or below $30,000 awarded to foreign vendors for work performed outside the United States, if it is impractical to obtain SAM registration; and
   * * * * *
(c) Contracting officers shall use the legal business name or “doing business as” name and physical address from the contractor’s SAM registration for the provided unique entity identifier to identify the contractor in section A of the contract schedule, similar sections of non-uniform contract formats and agreements, and all corresponding forms and data exchanges. Contracting officers shall make no changes to the data retrieved from SAM.
(d)(1)(i) If a contractor has legally changed its business name or “doing business as” name ( whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in subpart 42.12, the contractor is required to provide the responsible contracting officer a minimum of one business day’s written notification of its intention to change the name in SAM, comply with the requirements of subpart 42.12, and agree in writing to the timeline and procedures specified by the responsible contracting officer. Along with the notification the contractor is required to provide the contracting officer sufficient documentation to support the legally changed name.
   (ii) If the contractor fails to comply with the requirements of paragraph (d)(1)(i) of the clause at 52.204–13, System for Award Management Maintenance, or fails to perform the agreement at 52.204–13, paragraph (d)(1)(i)(C), and, in the absence of a properly executed novation or change-of-name agreement, the SAM information that shows the contractor to be other than the contractor indicated in the contract will be considered to be incorrect information within the meaning of the “Suspension of Payment” paragraph of the EFT clause of the contract.
   * * * * *
7. Revise section 4.1103 to read as follows:

4.1103 Procedures.
(a) Unless the acquisition is exempt under 4.1102(a), the contracting officer—
   (1) Shall verify that the offeror or quoter is registered in SAM (see paragraph (b) of this section) at the time an offer or quotation is submitted;
   (2) Should use the unique entity identifier to verify SAM registration—
   (i) Via https://www.sam.gov; or
   (ii) As otherwise provided by agency procedures; or
   (3) Need not verify SAM registration before placing an order or call if the contract or agreement includes the provision at 52.204–7, System for Award Management, or the clause at 52.212–4, Contract Terms and Conditions—Commercial Items, or a similar agency clause, except when use of the Government-wide commercial purchase card is contemplated as a method of payment. (See 32.1108(b)(2).)
   (b) If the contract action is being awarded in accordance with 4.1102(a)(5), the contractor is required to be registered in SAM within 30 days after contract award, or at least three days prior to submission of the first invoice, whichever occurs first.
   (c) Agencies shall protect against improper disclosure of information contained in SAM.
   (d) The contracting officer shall, on contractual documents transmitted to the payment office, provide the unique entity identifier, or, if applicable, the Electronic Funds Transfer indicator, in accordance with agency procedures.

4.1104 [Amended]

9. Revise section 4.1105 to read as follows:

4.1105 Solicitation provision and contract clauses.
(a)(1) Insert the provision at 52.204–7, System for Award Management, in all solicitations except when the conditions in 4.1102(a) apply.
   (2) Insert the provision at 52.204–7, System for Award Management, with its Alternate I when the solicitation is anticipated to be awarded in accordance with 4.1102(a)(5).
   (b) Insert the clause at 52.204–13, System for Award Management
Maintenance, in solicitations that contain the provision at 52.204–7, and resulting contracts.

10. Revise section 4.1201 to read as follows:

4.1201 Policy.

(a) Offerors and quoters are required to complete electronic annual certifications and certifications in SAM accessed via https://www.sam.gov as a part of required registration (see FAR 4.1102).

(b)(1) All registrants are required to review and update the representations and certifications submitted to SAM as necessary, but at least annually, to ensure they are kept current, accurate, and complete. The representations and certifications are effective until one year from the date of submission or update to SAM.

(2) A contractor that represented itself as a small business prior to award of a contract must update the representations and certifications in SAM in accordance with 52.219–28. A contractor that represented itself as other than small business before contract award and qualifies as a small business may update its representations and certifications in SAM in accordance with 52.219–28.

(c) Data in SAM is archived and is electronically retrievable. Therefore, when a prospective contractor has completed representations and certifications electronically in SAM, the contracting officer must reference the date of SAM verification in the contract file to satisfy contract documentation requirements of 4.803(a)(11). However, if an offeror identifies changes to SAM data pursuant to the FAR provisions at 52.204–8(d) or 52.212–3(b), the contracting officer must include a copy of the changes in the contract file.

(d) The contracting officer shall incorporate the representations and certifications by reference in the contract (see 52.204–19, or for acquisitions of commercial items see 52.212–4(v)).

11. Amend section 4.1202 by revising paragraph (a) introductory text to read as follows:

4.1202 Solicitation provision and contract clause.

(a) Insert the provision at 52.204–8, Annual Representations and Certifications, in solicitations, except for commercial item solicitations issued under FAR part 12. The contracting officer shall check the applicable provisions at 52.204–8(c)(2). When the provision at 52.204–7, System for Award Management, is included in the solicitation, do not separately include the following representations and certifications:

PART 7—ACQUISITION PLANNING

7.103 [Amended]


PART 8—REQUIRED SOURCES OF SUPPLIES AND SERVICES

8.402 [Amended]

13. Amend section 8.402 by removing from paragraph (g) “database”.

PART 9—CONTRACTOR QUALIFICATIONS

9.109–2 [Amended]


9.109–4 [Amended]

15. Amended section 9.109–4 by removing from paragraph (b) “database”.

9.109–8 [Amended]

16. Amend section 9.109–8 by—

(a) Revising paragraph (a);

(b) Removing paragraph (b)(1); and

(c) Adding the following and removing from paragraph (b)(2) “The SAM Exclusions” and adding “an exclusion record in SAM” in its place;

(d) Removing from paragraph (b)(1) “of all contractors debarred” and adding “of the entities debarred” in its place;

(e) Revising paragraph (c); and

(f) Removing from paragraph (d) “https://www.acquisition.gov” and adding “https://www.sam.gov” in its place.

The revisions read as follows:

9.404 Exclusions in the System for Award Management.

(a) * * * * * (1) Operates the web-based System for Award Management (SAM), which contains exclusion records; and * * * * *

(c) Each agency shall—

(1) Identify the individual(s) responsible for entering and updating exclusion data in SAM and assign the appropriate roles;

(2) Remove the exclusion roles in SAM when the individual leaves the organization or changes functions;

(3) For each exclusion accomplished by the Agency—

(i) Enter the information required by paragraph (b) of this section within 3 working days after the action becomes effective;

(ii) Determine whether it is legally permitted to enter the SSN, EIN, or other TIN, under agency authority to suspend or debar; and

(iii) Update the exclusion record in SAM, generally within 5 working days after modifying or rescinding an action;

(4) In accordance with internal retention procedures, maintain records relating to each debarment, suspension, or proposed debarment taken by the agency;

(5) Establish procedures to ensure that the agency does not solicit offers from, award contracts to, or consent to subcontracts with contractors who have an active exclusion record in SAM, except as otherwise provided in this subpart;

(6) Direct inquiries concerning listed contractors and other entities to the agency or other authority that took the action; and

(7) Contact GSA for technical assistance with SAM, via the support email address or on the technical support phone line.

PART 12—ACQUISITION OF COMMERCIAL ITEMS

19. Amend section 12.301 by—
PART 18—EMERGENCY ACQUISITIONS

24. Revise section 18.102 to read as follows:

18.102 System for Award Management.

(a) In accordance with 4.1102, contractors are not required to be registered in the System for Award Management (SAM) at the time of submission of offers or quotations for—

(1) Contracts awarded without providing for full and open competition due to unusual and compelling urgency (see 6.302–2); or

(2) Contracts awarded by a contracting officer—

(i) Deployed in the course of military operations;

(ii) Located outside the United States and its outlying areas, for work to be performed in support of diplomatic or developmental operations, in an area that has been designated by the Department of State as a danger pay post; or

(iii) In the conduct of emergency operations.

(b) However, contractors are required to be registered in SAM in order to gain access to the Disaster Response Registry.

(c) Contracting officers shall consult the Disaster Response Registry via https://www.sam.gov, Search Records, Advanced Search, Disaster Response Registry Search to determine the availability of contractors for debris removal, distribution of supplies, reconstruction, and other disaster or emergency relief activities inside the United States and outlying areas. (See 26.205).

PART 19—SMALL BUSINESS PROGRAMS

19.308 [Amended]

25. Amend section 19.308 by removing from paragraph (i)(3)(iii) “the System for Award Management (SAM)” and adding “SAM” in its place.

19.703 [Amended]

26. Amend section 19.703 by removing from paragraph (d)(1) introductory text “database”.

PART 22—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

27. Amend section 22.1025 by revising the first sentence to read as follows:

22.1025 Ineligibility of violators.

Persons or firms found to be in violation of the Service Contract Labor Standards statute will have an active exclusion record contained in the System for Award Management (see 9.404).

PART 23—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG–FREE WORKPLACE

23.802 [Amended]

28. Amend section 23.802 by removing from paragraph (d) introductory text “database”.

PART 25—FOREIGN ACQUISITION

29. Amend section 25.703–3 by revising paragraph (a) to read as follows:

25.703–3 Prohibition on contracting with entities that export sensitive technology to Iran.

(a) The head of an executive agency may not enter into or extend a contract for the procurement of goods or services with a person that exports certain sensitive technology to Iran, as determined by the President, and has an active exclusion in the System for Award Management at http://www.sam.gov (22 U.S.C. 8515).

PART 26—OTHER SOCIOECONOMIC PROGRAMS

26.205 [Amended]


PART 28—BONDS AND INSURANCE

31. Amend section 28.203–7 by revising paragraph (c) and removing from paragraph (d) “the System for Award Management Exclusions (see 9.404)” and adding “an active exclusion record in the System for Award Management (see 9.404),” in its place.

The revision reads as follows:

28.203–7 Exclusion of individual sureties.

(c) An individual surety excluded pursuant to this subsection shall be entered as an exclusion in the System for Award Management (see 9.404).
PART 32—CONTRACT FINANCING

32.1108 [Amended]

■ 32. Amend section 32.1108 by removing from paragraph (b)(2)(i) “(by looking in the System for Award Management (SAM))” and adding “(by looking in the System for Award Management (SAM))” in its place.
■ 33. Amend section 32.1110 by revising paragraph (a)(1) introductory text and removing from (a)(2)(i) “the SAM database” and adding “SAM” in its place.

The revision reads as follows:

32.1110 Solicitation provision and contract clauses.

(a) * * *

(1) 52.232–33. Payment by Electronic Funds Transfer—System for Award Management, in solicitations and contracts that include the provision at 52.204–7, System for Award Management, or an agency clause that requires a contractor to be registered in SAM and maintain registration until final payment, unless—

PART 44—SUBCONTRACTING POLICIES AND PROCEDURES

34. Amend section 44.202–2 by revising paragraph (a)(13) to read as follows:

44.202–2 Considerations.

(a) * * *

(13) Is the proposed subcontractor listed as excluded in the System for Award Management (see subpart 9.4)?

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

35. Amend section 52.204–7 by—
■ a. Revising the date of the provision;
■ b. In paragraph (a), revising the defined term “Registered in the System for Award Management (SAM) database” to read “Registered in the System for Award Management (SAM)”; and
■ c. Removing from paragraphs (a)(1) and (2) “the SAM database”; and adding “SAM” in their places;
■ d. Revising paragraph (b)(1);
■ e. Removing from paragraph (b)(2) “the SAM database” and adding “SAM” in its place;
■ f. Revising paragraph (d);
■ g. Removing paragraphs (e) and (f); and
■ h. Revising the date of Alternate I and paragraph (b)(1).

The revisions read as follows.

52.204–7 System for Award Management (Oct 2018)

* * * * *

(b)(1) An Offeror is required to be registered in SAM when submitting an offer or quotation, and shall continue to be registered until time of award, during performance, and through final payment of any contract, basic agreement, basic ordering agreement, or blanket purchasing agreement resulting from this solicitation.

* * * * *

(d) Processing time should be taken into consideration when registering. Offerors who are not registered in SAM should consider applying for registration immediately upon receipt of this solicitation. See https://www.sam.gov for information on registration.

(End of provision)

Alternate I (Oct 2018).

* * *

(b)(1) An Offeror is required to be registered in SAM as soon as possible. If registration is not possible when submitting an offer or quotation, the awardee shall be registered in SAM in accordance with the requirements of clause 52.204–13, System for Award Management Maintenance.

36. Amend section 52.204–8 by revising the date of the provision and paragraphs (b)(2) introductory text and (d) to read as follows:

52.204–8 Annual Representations and Certifications.

* * * * *

Annual Representations and Certifications (Oct 2018)

* * * * *

(b) * * *

(2) If the provision at 52.204–7, System for Award Management, is not included in this solicitation, and the Offeror has an active registration in the System for Award Management (SAM), the Offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The Offeror shall indicate which option applies by checking one of the following boxes:

* * * * *

(d) The Offeror has completed the annual representations and certifications electronically in SAM accessed through https://www.sam.gov. After reviewing the SAM information, the Offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

* * * * *

PART 54—FIRST-TIER SUBCONTRACT AWARD DATA SYSTEM (FSRS) REPORTING

37. Amend section 52.204–10 by—

■ a. Revising the date of the clause;
■ b. Removing from paragraph (d)(1) introductory text “database”; and
■ c. Revising paragraph (h).

The revisions read as follows:

52.204–10 Reporting Executive Compensation and First-Tier Subcontract Awards.

* * * * *

(h) The FSRS database at http://www.fsrs.gov will be prepopulated with some information from SAM and the FPDS database. If FPDS information is incorrect, the contractor should notify the contracting officer. If the SAM information is incorrect, the contractor is responsible for correcting this information.

* * * * *

38. Amend section 52.204–13 by—

■ a. Revising the date of the clause;
■ b. In paragraph (a), revising the defined term “Registered in the System for Award Management (SAM) database” to read “Registered in the System for Award Management (SAM)”;
■ c. Removing from paragraphs (a)(1) and (2) “the SAM database” and adding “SAM” in their places;
■ d. Redesignating paragraphs (b) through (d) as paragraphs (c) through (e);
■ e. Adding a new paragraph (b);
■ f. Revising newly redesignated paragraphs (c) and (d)(1)(i) introductory text;
■ g. Removing from newly redesignated paragraph (d)(1)(i)(A) “the SAM database” and adding “SAM” in its place;
■ h. Removing from newly redesignated paragraph (d)(1)(ii) “(c)(1)(i)” and “(c)(1)(i)(C)” and adding “(d)(1)(i)” and “(d)(1)(i)(C)” in their places, respectively;
i. Removing from newly redesignated paragraph (d)(2) “in the SAM” and adding “in SAM” in its place; and


The addition and revisions read as follows:

52.204–13 System for Award Management Maintenance.
* * * * *

(b) If the solicitation for this contract contained the provision 52.204–7 with its Alternate I, and the Contractor was unable to register prior to award, the Contractor shall be registered in SAM within 30 days after award or before three days prior to submission of the first invoice, whichever occurs first.

(c) The Contractor shall maintain registration in SAM during contract performance and through final payment of any contract, basic agreement, basic ordering agreement, or blanket purchasing agreement. The Contractor is responsible for the currency, accuracy and completeness of the data within SAM, and for any liability resulting from the Government’s reliance on inaccurate or incomplete data. To remain registered in SAM after the initial registration, the Contractor is required to review and update on an annual basis, from the date of initial registration or subsequent updates, its information in SAM to ensure it is current, accurate and complete.

Updating information in SAM does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(d) * * * *(1) * * *

(i) If a Contractor has legally changed its business name or “doing business as” name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in subpart 42.12, the Contractor shall provide the responsible Contracting Officer a minimum of one business day’s written notification of its intention to—* * * *

39. Amend section 52.209–7 by revising the date of the provision and removing from paragraph (d) “Management database via https://www.acquisition.gov” and adding “Management, which can be accessed via https://www.sam.gov” in its place.

The revision reads as follows:

52.209–7 Information Regarding Responsibility Matters.
* * * * *

Information Regarding Responsibility Matters (Oct 2018)
* * * * *


The revision reads as follows:

* * * * *

Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018)
* * * * *

41. Amend section 52.212–1 by—

a. Revising the date of provision;

b. Removing from paragraph (j) “(SAM) database” and adding “(SAM)” in its place; and

c. Removing and reserving paragraph (k).

The revision reads as follows:

52.212–1 Instructions to Offerors—Commercial Items.
* * * * *

Instructions to Offerors—Commercial Items (Oct 2018)
* * * * *

42. Amend section 52.212–3 by—

a. Revising the date and the introductory text of the provision;

b. Revising paragraph (b);

c. Removing from paragraph (l) introductory text “the SAM database” and adding “SAM” in its place; and

d. Removing from paragraph (t) introductory text “(52.212–1(k))” and adding “(12.301(d)(1))” in its place.

The revisions read as follows:

52.212–3 Offeror Representations and Certifications—Commercial Items.
* * * * *

Offeror Representations and Certifications—Commercial Items (Oct 2018)
* * * * *

The Offeror shall complete only paragraph (b) of this provision if the Offeror has completed the annual representations and certification electronically in the System for Award Management (SAM) accessed through https://www.sam.gov. If the Offeror has not completed the annual representations and certifications electronically, the Offeror shall complete only paragraphs (c) through (u) of this provision.
* * * * *

(b)(1) Annual Representations and Certifications. Any changes provided by the Offeror in paragraph (b)(2) of this provision do not automatically change the representations and certifications in SAM.

(2) The Offeror has completed the annual representations and certifications electronically in SAM accessed through http://www.sam.gov. After reviewing SAM information, the Offeror verifies by submission of this offer that the representations and certifications currently posted electronically at FAR 52.212–3, Offeror Representations and Certifications—Commercial Items, have been entered or updated in the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), at the time this offer is submitted and are incorporated in this offer by reference (see FAR 4.1201), except for paragraphs ___.

[Offeror to identify the applicable paragraphs at (c) through (u) of this provision that the offeror has completed for the purposes of this solicitation only, if any.]

These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted electronically on SAM.

43. Amend section 52.212–4 by revising the date of the clause and removing and reserving paragraph (t).

The revision reads as follows:

52.212–4 Contract Terms and Conditions—Commercial Items.
* * * * *

Contract Terms and Conditions—Commercial Items (Oct 2018)
* * * * *

44. Amend section 52.212–5 by—

a. Revising the date of the clause and paragraphs (b)(4), (b)(9), (b)(16), (b)(55), (e)(1)(iv), Alternate II heading and introductory text, and paragraph (e)(1)(ii)(D) of Alternate II to read as follows:
52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items.

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (Oct 2018)

* * * * *


* * * * *


* * * * *

(16) 52.219–8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).

* * * * *


* * * * *

(e)(1) * * *

(iv) 52.219–8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $700,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219–8 in lower tier subcontracts that offer further subcontracting opportunities.

* * * * *

Alternate II (Oct 2018). As prescribed in 12.301(b)(4)(ii), substitute the following paragraphs (d)(1) and (e)(1) for paragraphs [d](1) and (e)(1) of the basic clause as follows:

* * * * *

(e)(1) * * *

(ii) * * *

[D] 52.219–8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $700,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219–8 in lower tier subcontracts that offer subcontracting opportunities.

* * * * *

52.213–4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items) (Oct 2018)

* * * * *

Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items) (Oct 2018)

(a) * * *

(2) * * *

(viii) 52.244–6, Subcontracts for Commercial Items (Oct 2018).

* * * * *

(b) * * *

(1) * * *


* * * * *

(xix) 52.232–33, Payment by Electronic Funds Transfer—System for Award Management (SAM) as its source of EFT information).

* * * * *

46. Amend section 52.219–8 by revising the date of the clause and removing from paragraph (d)(5) introductory text “database”.

The revision reads as follows:

52.219–8 Utilization of Small Business Concerns.

* * * * *

Utilization of Small Business Concerns (Oct 2018)

* * * * *

47. Amend section 52.232–33 by—

a. Revising the date of the clause;

b. Removing from paragraph (b) “(SAM) database” and “the SAM database” and adding “(SAM)” and “SAM” in their places, respectively;

c. Removing from paragraph (d) “the SAM database” and adding “SAM” in two places; and

d. Removing from paragraphs (g) and (i) “the SAM database” and adding “SAM” in their places, respectively.

The revision reads as follows:

52.232–33 Payment by Electronic Funds Transfer—System for Award Management.

* * * * *

Payment by Electronic Funds Transfer—System for Award Management (Oct 2018)

* * * * *

48. Amend section 52.244–6 by revising the date of the clause and paragraph (c)(1)(vi) to read as follows:

* * * * *

Subcontracts for Commercial Items (Oct 2018)

* * * * *

(c)(1) * * *

(vi) 52.219–8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)), if the subcontract offers further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $700,000 ($1.5 million for construction of any public facility), the subcontractor must include 52.219–8 in lower tier subcontracts that offer subcontracting opportunities.

* * * * *

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 37 and 52

[FAC 2005–101; FAR Case 2018–009; Item II; Docket No. 2018–0009; Sequence No. 1] RIN 9000–AN70

Federal Acquisition Regulations: One Dollar Coins

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement a section of the National Defense Authorization Act for Fiscal Year 2018 that provides an exception for business operations conducted by a contractor while performing under a Government contract from the requirement to accept and dispense $1 coins.

DATES: Effective October 26, 2018.


SUPPLEMENTARY INFORMATION:
I. Background

In August of 2007, FAR 37.116 implemented section 104 of the Presidential $1 Coin Act of 2005 (31 U.S.C. 5112(p)(1); Pub. L. 109–145), which removed barriers to the circulation of $1 coins. Section 104 requires that business operations performed on Government premises provide for accepting and dispensing of existing and proposed $1 coins as part of operations on and after January 1, 2008. To implement this requirement, FAR clause 52.237–11, Accepting and Dispensing of $1 Coin, was created for inclusion in solicitations and contracts for services that involve business operations conducted in U.S. coins and currency on any premises owned by the U.S. or under the control of any agency or instrumentality of the U.S. The clause requires contractors to be capable of accepting and dispensing $1 coins as part of business operations under the contract.

The Section 809 Panel is a congressionally mandated panel to streamline and improve the acquisition process by identifying and eliminating outdated acquisition provisions. As part of this process, the Section 809 Panel made recommendations to amend outdated acquisition laws. One of the Panel’s recommendations was to amend the Presidential $1 Coin Act of 2005 because the intention of the Act was to increase circulation of the $1 coin, which is not directly related to agencies’ missions. As a result of the Panel’s recommendation, section 885 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2018 provides an exception for business operations conducted by a contractor while performing under a Government contract from the requirements to accept and dispense $1 coins.

The FAR is amended as follows to implement section 885 of the NDAA for FY 2018:

A. FAR sections 37.116 through 37.116–2 are removed.
B. Paragraph (c)(11) is removed from the clause at FAR 52.237–11, Accepting and Dispensing of $1 Coin, is removed.

II. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Items, Including Commercially Available Off-the-Shelf Items (COTS)

The clause at FAR 52.237–11, Accepting and Dispensing of $1 Coin, is being removed. It applied to contracts at or below the SAT, and to commercial items, including COTS.

III. Publication of This Final Rule for Public Comment Is Not Required by Statute

“Publication of proposed regulations”, 41 U.S.C. 1707, is the statute which applies to the publication of the Federal Acquisition Regulation. Paragraph (a)(1) of the statute requires that a procurement policy, regulation, procedure or form (including an amendment or modification thereof) must be published for public comment if it relates to the expenditure of appropriated funds, and has either a significant effect beyond the internal operating procedures of the agency issuing the policy, regulation, procedure, or form, or has a significant cost or administrative impact on contractors or offerors. This final rule is not required to be published for public comment, because it merely removes the requirement in the FAR for business operations performing Government contracts to accept and dispense $1 coins. It does not have a significant effect on the public.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 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, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

V. Executive Order 13771

This rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

VI. Regulatory Flexibility Act

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 41 U.S.C. 1707(a)(1) (see section III of this preamble), the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

VII. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 37 and 52

Government procurement.

Dated: September 17, 2018.

William F. Clark,
Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 37 and 52 as set forth below:

1. The authority citation for parts 37 and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113

PART 37—SERVICE CONTRACTING

37.116 [Removed]

2. Remove section 37.116.

37.116–1 [Removed]


37.116–2 [Removed]


PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

5. Amend section 52.212–5 by revising the date of the clause and removing paragraph (c)(11)

The revision reads as follows:

52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items.

Contract Terms and Conditions Required To Implement Statutes or Executive Orders— Commercial Items (Oct 2018)

52.237–11 [Removed]

6. Remove section 52.237–11.

[FR Doc. 2018–20709 Filed 9–25–18; 8:45 am]

BILLING CODE 6820–EP–P
DEPARTMENT OF DEFENSE
GENERAL SERVICES ADMINISTRATION
NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1
[Docket No. FAR 2018–0001, Sequence No. 5]

Federal Acquisition Regulation:
Federal Acquisition Circular 2005–101;
Small Entity Compliance Guide

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small Entity Compliance Guide.

SUMMARY: This document is issued under the joint authority of DoD, GSA, and NASA. This Small Entity Compliance Guide has been prepared consistent with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It consists of a summary of the rules appearing in Federal Acquisition Circular (FAC) 2005–101, which amends the Federal Acquisition Regulation (FAR). An asterisk (*) next to a rule indicates that a regulatory flexibility analysis has been prepared. Interested parties may obtain further information regarding these rules by referring to FAC 2005–101, which precedes this document. These documents are also available via the internet at http://www.regulations.gov.

DATES: September 26, 2018.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact the analyst whose name appears in the table below. Please cite FAC 2005–101 and the FAR case number. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755.

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SUPPLEMENTARY INFORMATION:
Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these rules, refer to the specific item numbers and subjects set forth in the documents following these item summaries. FAC 2005–101 amends the FAR as follows:

**Item I—System for Award Management Registration (FAR Case 2015–005)**

This final rule updates the instructions for registration in the System for Award Management (SAM) and corrects an inconsistency involving the timing of registration. In order to correct this inconsistency, the final rule amends FAR 4.1102, 4.1103, and 52.204–7 to require (with some exceptions) offeror registration in SAM prior to submission of an offer.

In addition, the rule requires contracting officers to use the name and physical address from the contractor’s SAM registration for the provided “unique entity identifier”; removes the term “division name” from the FAR text at FAR 4.1102 and clause 52.204–13; and changes the referenced website “acquisition.gov” to “sam.gov” to be consistent with the rest of the FAR. It is not anticipated that the rule will have a significant economic impact on small entities, because the rule only clarifies that offerors must be registered in SAM prior to submission of an offer, which is already necessary in order to submit the required annual representations and certifications with the offer.

**Item II—One Dollar Coins (FAR Case 2018–009)**

This final rule amends the FAR to implement section 885 of the National Defense Authorization Act for Fiscal Year 2018 (Pub. L. 115–91). Section 885 amends 31 U.S.C. 5112(p) to provide an exception for business operations conducted in U.S. coins and currency will no longer be required to accept $1 coins.

Contracting officers will no longer have to insert FAR clause 52.237–11, Accepting and Dispensing of $1 Coin, into solicitations and contracts.

Contractors providing services under Government contracts that involve business operations conducted in U.S. coins and currency will no longer be required to accept $1 coins.

The Regulatory Flexibility Act does not apply to this rule, because this final rule does not constitute a significant FAR revision within the meaning of FAR 1.501–1, and 41 U.S.C. 1707 does not require publication for public comment.

Dated: September 17, 2018.

William F. Clark,
Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[PR Doc. 2018–20710 Filed 9–25–18; 8:45 am]

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