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Presidential Documents

Title 3—

The President

Executive Order 13895 of October 22, 2019

President's Council of Advisors on Science and Technology

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to establish an advisory council on science and technology, it is hereby ordered as follows:

Section 1. *Purpose.* In every age of our Nation's history, American ingenuity has driven technological progress and the promise of the American Dream. Scientific advancement has improved the lives of our citizens, created jobs and better futures for American workers, and kept the American people safe at home and abroad. American thinkers, inventors, and entrepreneurs, empowered by free-market capitalism and driven by bold ideas, have created an ecosystem of innovation that is the envy of the world, making our Nation prosperous and strong.

Since World War II, our Nation's greatest scientists and engineers have advised the Federal Government, guiding the United States through the nuclear age, the mission to the moon, and the transformations of the digital revolution. Emerging technologies like artificial intelligence and quantum information science are now on the horizon, and how we address their development will determine whether they give rise to new American industries or challenge American values. With American leadership facing fierce global competition, today more than ever our Nation is in need of new approaches for unleashing the creativity of our research enterprise and empowering private sector innovation to ensure American technological dominance.

Through collaborative partnerships across the American science and technology enterprise, which includes an unmatched constellation of public and private educational institutions, research laboratories, corporations, and foundations, the United States can usher extraordinary new technologies into homes, hospitals, and highways across the world. These technologies would have American values at their core. By strengthening the ties that connect government, industry, and academia, my Administration will champion a new era of American research and innovation, which will give rise to new discoveries that create the industries of the future.

Sec. 2. *Establishment.* The President's Council of Advisors on Science and Technology (PCAST) is hereby established. The PCAST shall be composed of the Director of the Office of Science and Technology Policy (the ''Director''), and not more than 16 additional members appointed by the President. These additional members shall include distinguished individuals from sectors outside of the Federal Government. They shall have diverse perspectives and expertise in science, technology, education, and innovation. The Director shall serve as the Chair of the PCAST.

Sec. 3. *Functions.* (a) The PCAST shall advise the President on matters involving science, technology, education, and innovation policy. The Council shall also provide the President with scientific and technical information that is needed to inform public policy relating to the American economy, the American worker, national and homeland security, and other topics. The PCAST shall meet regularly and shall:

(i) respond to requests from the President or the Director for information, analysis, evaluation, or advice;

(ii) solicit information and ideas from a broad range of stakeholders on contemporary topics of critical importance to the Nation in order to inform policy making. Stakeholders include the research community, the private sector, universities, national laboratories, State and local governments, and non-profit organizations;

(iii) serve as the advisory committee identified in subsection 101(b) of the High-Performance Computing Act of 1991 (Public Law 102–194), as amended (15 U.S.C. 5511(b)). In performing the functions of such advisory committee, the PCAST shall be known as the President's Innovation and Technology Advisory Committee; and

(iv) serve as the advisory panel identified in section 4 of the 21st Century Nanotechnology Research and Development Act (Public Law 108–153), as amended (15 U.S.C. 7503). In performing the functions of such advisory committee, the PCAST shall be known as the National Nanotechnology Advisory Panel.

(b) The PCAST shall provide advice to the National Science and Technology Council in response to requests from that Council.

Sec. 4. *Administration.* (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide the PCAST with information concerning scientific and technological matters when requested by the PCAST Chair.

(b) In consultation with the Director, the PCAST may create standing subcommittees and ad hoc groups, including technical advisory groups to assist the PCAST and provide preliminary information to the PCAST.

(c) The Director may request that members of the PCAST, its standing subcommittees, or ad hoc groups who do not hold a current clearance for access to classified information, receive security clearance and access determinations pursuant to Executive Order 12968 of August 2, 1995 (Access to Classified Information), as amended, or any successor order.

(d) The Department of Energy shall provide such funding and administrative and technical support as the PCAST may require.

(e) Members of the PCAST shall serve without any compensation for their work on the PCAST, but may receive travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the government service (5 U.S.C. 5701–5707).

Sec. 5. *Termination.* The PCAST shall terminate 2 years from the date of this order unless extended by the President.

Sec. 6. *General Provisions.* (a) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. App.) (FACA), may apply to the PCAST, any functions of the President under the FACA, except that of reporting to the Congress, shall be performed by the Secretary of Energy in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) Nothing in this order shall be construed to impair or otherwise affect:

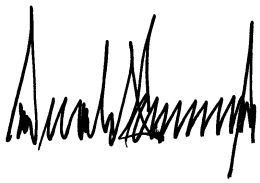
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 7. *Revocation.* Executive Order 13539 of April 21, 2010 (President's Council of Advisors on Science and Technology), as amended, is hereby revoked.



THE WHITE HOUSE,
October 22, 2019.

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Rules and Regulations

Federal Register

Vol. 84, No. 207

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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.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0523; Product Identifier 2019–NM–050–AD; Amendment 39–19768; AD 2019–21–02]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A330–200, –200F, and –300 series airplanes. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 29, 2019.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of November 29, 2019.

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAW, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* 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–2019–0523.

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–2019–0523; 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 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: Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3229.

SUPPLEMENTARY INFORMATION:

Discussion

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0049, dated March 11, 2019 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus SAS Model A330–200, –200F, and –300 series airplanes. You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0523.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A330–200, –200F, and –300 series airplanes. The NPRM published in the **Federal Register** on July 9, 2019 (84 FR 32661). The NPRM was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA is issuing this AD to address a safety-significant latent failure (that is not annunciated) that, in combination with one or more other specific failures or events, could result in a hazardous or catastrophic failure condition. See the MCAI for additional background information.

Comments

The FAA 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.

Request To Add Service Information

American Airlines (AAL) asked that the proposed AD be revised to include Airbus A330 Airworthiness Limitations Section (ALS) Part 3—Certification Maintenance Requirements (CMR), Variation 6.1, dated June 28, 2019, as an additional source of service information. AAL stated that the variation document provides relieving compliance times for certain tasks. AAL pointed out that an alternative method of compliance (AMOC) for AD 2016–26–05, Amendment 39–18763 (82 FR 1170, January 5, 2017) (''AD 2016–26–05'') (AMOC AIR–676–19–016, dated November 2, 2018), has been approved to allow incorporation of the variation document into AAL's maintenance program as acceptable for compliance with the requirements of paragraph (g) of the proposed AD.

The FAA agrees with the commenter's request for the reason provided. Paragraph (g) of this AD has been revised to include Airbus A330 ALS Part 3—Certification Maintenance Requirements (CMR), Variation 6.1, dated June 28, 2019, as an additional source of service information.

Request To Allow the Use of Future Revisions of Service Information

Delta Airlines (DAL) asked that the proposed AD be revised to allow the use of future revisions of the service information. DAL noted that since the FAA has started to instruct operators to refer to the EASA AD to comply with the FAA AD, it recommends that the FAA include a paragraph that resolves this issue by referring to the EASA AD. DAL added that the EASA AD allows the use of future revisions of service information.

The FAA acknowledges the commenter's observation regarding the FAA's new ''IBR the MCAI'' process,

which uses EASA ADs as the primary source of information for compliance with corresponding FAA ADs. However, the FAA currently only uses the new ''IBR the MCAI'' process with certain MCAI ADs (primarily those with service bulletins as the primary source of information). When the Airbus A330 Airworthiness Limitations Section is revised, and EASA issues an AD, the FAA will consider drafting the corresponding FAA AD as an ''IBR the MCAI'' AD. Thus, all provisions specified in the EASA AD would apply to the corresponding FAA AD.

Based on the information above, the FAA does not agree with the commenter's request to allow the use of future revisions of the service information. The FAA may not refer to any document that does not yet exist in an AD. To allow operators to use later revisions of the referenced document (issued after AD publication), the most expeditious approach would be for operators to request approval to use later revisions as an alternative method of compliance with this AD, under the provisions of paragraph (j)(1) of this AD. The alternative would be for the FAA to revise the AD to reference specific later revisions, which would take longer and consume more resources. This AD has not been revised regarding this issue.

Conclusion

The FAA reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule with the change described previously and minor editorial changes. The FAA has 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.

The FAA 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

Airbus SAS has issued the following service information.

- A330 Airworthiness Limitations Section (ALS) Part 3—Certification Maintenance Requirements (CMR), Revision 06, dated October 15, 2018. This service information describes maintenance instructions and airworthiness limitations, including updated inspections and intervals, to be incorporated into the existing maintenance or inspection program.
- A330 ALS Part 3—Certification Maintenance Requirements (CMR), Variation 6.1, dated June 28, 2019. This service information describes maintenance instructions and airworthiness limitations, and increases the flight cycle inspection intervals to 12,000 flight hours.

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

The FAA estimates that this AD affects 107 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. In the past, the FAA has estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the FAA estimates the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

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.

The FAA is 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) Will not affect intrastate aviation in Alaska, and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2019–21–02 Airbus SAS: Amendment 39–19768; Docket No. FAA–2019–0523 Product Identifier 2019–NM–050–AD.

(a) Effective Date

This AD is effective November 29, 2019.

(b) Affected ADs

This AD affects AD 2016–26–05, Amendment 39–18763 (82 FR 1170, January 5, 2017) (''AD 2016–26–05'').

(c) Applicability

This AD applies to Airbus SAS Model A330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes, certificated in any category, with an original certificate of airworthiness or original export certificate of airworthiness issued on or before October 15, 2018.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address a safety-significant latent failure (that is not annunciated) that, in combination with one or more other specific failures or events, could result in a hazardous or catastrophic failure condition.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision

Within 90 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in Airbus A330 Airworthiness Limitations Section (ALS) Part 3—Certification Maintenance Requirements (CMR), Revision 06, dated October 15, 2018, as supplemented by Airbus A330 ALS Part 3—Certification Maintenance Requirements (CMR), Variation 6.1, dated June 28, 2019. The initial compliance times for doing the tasks is at the time specified in Airbus A330 Airworthiness Limitations Section (ALS) Part 3—Certification Maintenance Requirements (CMR), Revision 06, dated October 15, 2018, as supplemented by Airbus A330 ALS Part 3—Certification Maintenance Requirements (CMR), Variation 6.1, dated June 28, 2019, or within 90 days after the effective date of this AD, whichever occurs later.

(h) No Alternative Actions or Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (j)(1) of this AD.

(i) Terminating Action for AD 2016–26–05

Accomplishing the actions required by this AD terminates all requirements of AD 2016–26–05.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards 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 International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* 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.

(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, International Section, Transport Standards Branch, FAA; or the European Union Aviation Safety Agency (EASA); or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) AD 2019–0049, dated March 11, 2019, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0523.

(2) For more information about this AD, contact Vladimir Ulyanov, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3229.

(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.

(i) Airbus A330 Airworthiness Limitations Section (ALS) Part 3—Certification Maintenance Requirements (CMR), Revision 06, dated October 15, 2018.

(ii) Airbus A330 ALS Part 3—Certification Maintenance Requirements (CMR), Variation 6.1, dated June 28, 2019.

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.*

(4) 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.

(5) 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, email *fedreg.legal@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on October 18, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–23284 Filed 10–24–19; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2017–0012]

16 CFR Part 1217

Revisions to Safety Standard for Toddler Beds

AGENCY: Consumer Product Safety Commission.

ACTION: Direct final rule.

SUMMARY: In February 2017, the U.S. Consumer Product Safety Commission (CPSC) published an update to the consumer product safety standard for toddler beds. The standard incorporated by reference the applicable ASTM voluntary standard. ASTM has since published two revised versions of the voluntary standard for toddler beds. We are publishing this direct final rule revising the CPSC's mandatory standard for toddler beds to incorporate by reference, the most recent version of the applicable ASTM standard.

DATES: The rule is effective on January 27, 2020, unless we receive significant adverse comment by November 25, 2019. If we receive timely significant adverse comments, we will publish notification in the **Federal Register**, withdrawing this direct final rule before its effective date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of January 27, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2017–0012, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. The CPSC does not accept comments submitted by electronic mail (email), except through *www.regulations.gov.* The CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions in the following way: Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions), preferably in five copies, to: Division of the Secretariat, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received may be posted without change, including

any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *www.regulations.gov,* and insert the docket number, CPSC–2017–0012, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Justin Jirgl, Compliance Officer, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814–4408; telephone: 301–504–7814; email: *jjirgl@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

1. Statutory Authority

Section 104(b)(1)(B) of the Consumer Product Safety Improvement Act (CPSIA), also known as the Danny Keysar Child Product Safety Notification Act, requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. The law requires these standards to be ''substantially the same as'' applicable voluntary standards or more stringent than the voluntary standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

The CPSIA also sets forth a process for updating CPSC's durable infant or toddler standards when the voluntary standard, upon which the CPSC standard was based, is changed. Section 104(b)(4)(B) of the CPSIA provides that if an organization revises a standard that has been adopted, in whole or in part, as a consumer product safety standard under this subsection, it shall notify the Commission. In addition, the revised voluntary standard shall be considered to be a consumer product safety standard issued by the Commission under section 9 of the Consumer Product Safety Act (15 U.S.C. 2058), effective 180 days after the date on which the organization notifies the Commission (or such later date specified by the Commission in the **Federal Register**) unless, within 90 days after receiving that notice, the Commission notifies the organization that it has determined that the proposed revision does not improve the safety of the consumer product covered by the standard and that the Commission is retaining the existing consumer product safety standard.

2. The Toddler Beds Standard

On April 20, 2011, the Commission published [1] a final rule issuing a mandatory standard for toddler beds that incorporated by reference the standard in effect at that time, ASTM F1821–09, *Standard Consumer Specification for Toddler Beds,* with certain modifications to make the standard more stringent. 76 FR 22019. The standard was codified in the Commission's regulations at 16 CFR part 1217.

ASTM has revised the toddler beds standards several times since issuance of the rule:

- On September 25, 2013, ASTM officially notified the CPSC that ASTM published a revised 2013 version of ASTM F1821. The Commission published a **Federal Register** notice revising the Commission's toddler bed standard to reference ASTM F1821–13, effective March 24, 2014 (78 FR 73692, December 9, 2013).
- On April 6, 2015, ASTM officially notified the CPSC that ASTM had revised ASTM's toddler bed standard again and had published a revised 2015 version of ASTM F1821. Due to an inadvertent omission in the revised ASTM standard, the Commission voted [2] unanimously to retain the existing consumer product safety standard.
- On December 8, 2016, ASTM officially notified the CPSC that it had published a revised 2016 version of ASTM F1821. The Commission published a **Federal Register** notice incorporating ASTM F1821–16, *Standard Consumer Safety Specifications for Toddler Beds,* effective June 6, 2017, in 16 CFR part 1217 as the safety standard for toddler beds. (82 FR 11317, February 22, 2017).

Since publication of ASTM F1821–16, the current mandatory standard, ASTM has published revised versions of ASTM F1821 in 2018 and 2019. These revised versions of the standard not only update the standard to reflect clarifications to testing for consistency, the revisions also harmonize the standard with other juvenile product standards. ASTM F1821–19 was approved and published in June 2019. ASTM officially notified the Commission of this revision on July 30, 2019. Recently, ASTM published an editorial version of the 2019 standard, ASTM F1821–19$^{\varepsilon 1}$, which corrects two typographical errors, but does not change the technical content of the 2019 version. The rule is incorporating ASTM F1821–19$^{\varepsilon 1}$ as the mandatory standard.

B. Revisions to the ASTM Standard

The ASTM standard for toddler beds, ASTM F1821–19$^{\varepsilon 1}$ defines a ''toddler bed'' as any bed sized to accommodate a full-size crib mattress having minimum dimensions of 51⅝ inches (1310 mm) in length and 27¼ inches (690 mm) in width and is intended to provide free access and egress to a child not less than 15 months of age and who weighs no more than 50 pounds (27.7 kg). The standard has provisions that address the following hazards: Entrapment in bed end structures, entrapment between the guardrail and side rail, and entrapment in the mattress support system. In addition, the ASTM standard has provisions addressing corner post extensions, which may catch cords, ribbons, necklaces or clothing. Under section 104(b)(4)(B) of the CPSIA, unless the Commission determines that ASTM's revision to a voluntary standard that is a CPSC mandatory standard ''does not improve the safety of the consumer product covered by the standard,'' the revised voluntary standard becomes the new mandatory standard. As discussed below, the Commission determines that the changes made in ASTM F1821–19$^{\varepsilon 1}$ will either improve the safety of toddler beds or are neutral with respect to safety. Therefore, the Commission will allow the revised voluntary standard to become effective as a mandatory consumer product safety standard under the statute, effective January 27, 2020.

We summarize the differences and the CPSC's assessment of the revisions to ASTM F1821 below.

1. Differences Between 16 CFR Part 1217 and ASTM F1821–18

ASTM F1821–18, was approved and published in December 2018, and was the first revision of the standard following ASTM F1821–16, the current mandatory standard. ASTM did not notify CPSC of this update because ASTM was waiting to make an additional change to the standard. ASTM F1821–18 made the following changes:

- Section 1.7 states ''This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate

[1] A correction notice was published (76 FR 27882, May 13, 2011) because the Office of the Federal Register inadvertently omitted the last two sections and figures from the April 20, 2011 **Federal Register** notice.

[2] *https://www.cpsc.gov/th/content/rca-astm%E2%80%99s-revisions-to-toddler-bed-standard.*

safety, health, and *environmental* practices and determine the applicability of regulatory limitations prior to use.'' (*Italicized* language was added to the standard). We conclude that adding the word ''environmental'' does not change the safety of toddler beds because this does not relate specifically to the toddler bed requirements.

• The 2018 version of the ASTM standard added language (Section 1.8), which ASTM intends to add to all of its standards, stating that ASTM developed the standard in accordance with principles recognized by the World Trade Organization. We conclude that adding this text does not change the safety of toddler beds because the language pertains to voluntary standards development generally.

• The terminology section has a new definition for corner posts, ''3.1.3 *corner post,* n—vertical post located at the corner of a product.'' This definition does not change any other aspects of the standard. Therefore, we conclude this addition is neutral to the safety of the toddler beds.

• An editorial change was made in section 7.8.3 deleting the period in ''15–lbf.'' to ''15–lbf'' We conclude this editorial change is neutral to toddler bed safety.

2. Differences Between 16 CFR Part 1217 and ASTM F1821–19$^{\varepsilon 1}$

ASTM F1821–19 contains changes to the performance requirements for section 6.2 *Mattress Support System Attachment and Side Rails Integrity,* as well as the testing requirements in section *7.3 Mattress Support System Attachment and Side Rails Integrity Tests.* Some toddler beds have separate mattress support systems and side rail attachments to the end structure, so this change clarified that both the mattress support system and the side rail attachments must be tested. The testing requirement provide specific instructions for the mattress support system (section 7.3.2) and the side rails (section 7.3.3). We consider the clarification of performance and test requirements for mattress support system attachment and side rails to be an improvement to the safety of toddler beds because the change removes ambiguity and it assures more consistent testing.

Section 7.3.3 *Side Rails* of ASTM F1821–19 incorporates the previous section 7.3.4 requirements into section 7.3.3.2. However, publication of ASTM F1821–19 included the previous section 7.3.4 requirements, thus repeating the section 7.3.3.2 requirements. ASTM published ASTM F1821–19$^{\varepsilon 1}$ to make two editorial corrections: Deleting section 7.3.4 and correcting the word ''load'' in section 7.3.3.2 to ''force.''

These editorial corrections do not change the voluntary standard requirements, but merely correct drafting errors, and therefore, the standard is simply noted with the epsilon.

C. Incorporation by Reference

The Office of the Federal Register (OFR) has regulations concerning incorporation by reference. 1 CFR part 51. Under these regulations, agencies must discuss, in the preamble to the final rule, ways that the materials the agency incorporates by reference are reasonably available to interested persons and how interested parties can obtain the materials. In addition, the preamble to the final rule must summarize the material. 1 CFR 51.5(b).

In accordance with the OFR's requirements, section B of this preamble summarizes the major provisions of the ASTM F1821–19$^{\varepsilon 1}$ standard that the Commission incorporates by reference into 16 CFR part 1217. The standard is reasonably available to interested parties, and interested parties may purchase a copy of the standard from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; phone: 610–832–9585; *www.astm.org.* A copy of the standard can also be inspected at CPSC's Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923.

D. Certification

Section 14(a) of the CPSA requires that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, be certified as complying with all applicable CPSC requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product, or on a reasonable testing program, or, for children's products, on tests on a sufficient number of samples by a third party conformity assessment body accredited by the Commission to test according to the applicable requirements. As noted, standards issued under section 104(b)(1)(B) of the CPSIA are ''consumer product safety standards.'' Thus, they are subject to the testing and certification requirements of section 14 of the CPSA.

Because toddler beds are children's products, samples of these products must be tested by a third party conformity assessment body whose accreditation has been accepted by the Commission. These products also must comply with all other applicable CPSC requirements, such as the lead content requirements in section 101 of the CPSIA, the phthalates prohibitions in section 108 of the CPSIA and 16 CFR part 1307, the tracking label requirement in section 14(a)(5) of the CPSA, and the consumer registration form requirements in section 104(d) of the CPSIA.

E. Notice of Requirements

In accordance with section 14(a)(3)(B)(iv) of the CPSIA, the Commission has previously published a notice of requirements (NOR) for accreditation of third party conformity assessment bodies for testing toddler beds (76 FR 22030, April 20, 2011). The NOR provided the criteria and process for our acceptance of accreditation of third party conformity assessment bodies for testing toddler beds to 16 CFR part 1217. The NORs for all mandatory standards for durable infant or toddler products are listed in the Commission's rule, ''Requirements Pertaining to Third Party Conformity Assessment Bodies,'' codified at 16 CFR part 1112.

Testing laboratories that have demonstrated competence for testing in accordance with ASTM F1821–16 have the competence to test in accordance with the revised standard ASTM F1821–19$^{\varepsilon 1}$. Therefore, the Commission considers the existing CPSC-accepted laboratories for testing to ASTM F1821–16 to be capable of testing to ASTM F1821–19$^{\varepsilon 1}$ as well. Therefore, the Commission considers the existing accreditations that the Commission has accepted for testing to this standard also to cover testing to the revised standard. Accordingly, the existing NOR for this standard will remain in place, and CPSC-accepted third party conformity assessment bodies are expected to update the scope of the testing laboratories' accreditation to reflect the revised standard in the normal course of renewing their accreditation.

F. Direct Final Rule Process

The Commission is issuing this rule as a direct final rule. Although the Administrative Procedure Act (APA) generally requires notice and comment rulemaking, section 553 of the APA provides an exception when the agency, for good cause, finds that notice and public procedure are ''impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(B). The Commission concludes that when the Commission updates a reference to an ASTM standard that the Commission has incorporated by reference under

section 104(b) of the CPSIA, notice and comment is not necessary.

Under the process set out in section 104(b)(4)(B) of the CPSIA, when ASTM revises a standard that the Commission has previously incorporated by reference as a Commission standard for a durable infant or toddler product under section 104(b)(1)(b) of the CPSIA, that revision will become the new CPSC standard, unless the Commission determines that ASTM's revision does not improve the safety of the product. Thus, unless the Commission makes such a determination, the ASTM revision becomes CPSC's standard by operation of law. The Commission is allowing ASTM F1821–19$^{\varepsilon 1}$ to become CPSC's new standard. The purpose of this direct final rule is merely to update the reference in the Code of Federal Regulations so that it reflects accurately the version of the standard that takes effect by statute. Public comment will not impact the substantive changes to the standard or the effect of the revised standard as a consumer product safety standard under section 104(b) of the CPSIA. Under these circumstances, notice and comment are not necessary. In Recommendation 95–4, the Administrative Conference of the United States (ACUS) endorsed direct final rulemaking as an appropriate procedure to expedite promulgating rules that are noncontroversial and that are not expected to generate significant adverse comment. *See* 60 FR 43108 (August 18, 1995). ACUS recommended that agencies use the direct final rule process when they act under the ''unnecessary'' prong of the good cause exemption in 5 U.S.C. 553(b)(B). Consistent with the ACUS recommendation, the Commission is publishing this rule as a direct final rule because we do not expect any significant adverse comments.

Unless we receive a significant adverse comment within 30 days, the rule will become effective on January 27, 2020. In accordance with ACUS's recommendation, the Commission considers a significant adverse comment to be one where the commenter explains why the rule would be inappropriate, including an assertion challenging the rule's underlying premise or approach, or a claim that the rule would be ineffective or unacceptable without change.

Should the Commission receive a significant adverse comment, the Commission would withdraw this direct final rule. Depending on the comments and other circumstances, the Commission may then incorporate the adverse comment into a subsequent direct final rule or publish a notice of proposed rulemaking, providing an opportunity for public comment.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that agencies review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603 and 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As explained, the Commission has determined that notice and comment are not necessary for this direct final rule. Thus, the RFA does not apply. We also note the limited nature of this document, which updates the incorporation by reference to reflect the mandatory CPSC standard that takes effect under section 104 of the CPSIA.

H. Paperwork Reduction Act

The standard for toddler beds contains information collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The revisions made no changes to that section of the standard. Thus, the revisions will not have any effect on the information collection requirements related to the standard.

I. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement because they ''have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

J. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as ''consumer product safety rules,'' thus, implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

K. Effective Date

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standard organization revises a standard upon which a consumer product safety standard was based, the revision becomes the CPSC standard within 180 days of notification to the Commission, unless the Commission determines that the revision does not improve the safety of the product, or the Commission sets a later date in the **Federal Register**. The Commission has not set a different effective date. Thus, in accordance with this provision, this rule takes effect 180 days after we received notification from ASTM of revision to this standard. As discussed in the preceding section, this is a direct final rule. Unless we receive a significant adverse comment within 30 days, the rule will become effective on January 27, 2020.

L. The Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that, before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The submission must indicate whether the rule is a ''major rule.'' The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a ''major rule.'' Pursuant to the CRA, OIRA designated this rule as not a ''major rule,'' as defined in 5 U.S.C. 804(2). In addition, to comply with the CRA, the Office of the General Counsel will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1217

Consumer protection, Imports, Incorporation by reference, Infants and children, Law enforcement, Safety, Toys.

For the reasons stated above, the Commission amends title 16 CFR chapter II as follows:

PART 1217—SAFETY STANDARD FOR TODDLER BEDS

■ 1. Revise the authority citation for part 1217 to read as follows:

Authority: Sec. 104, Pub. L. 110–314, 122 Stat. 3016 (15 U.S.C. 2056a); Sec 3, Pub. L. 112–28, 125 Stat. 273.

■ 2. Revise § 1217.2 to read as follows:

§ 1217.2 Requirements for toddler beds.

Each toddler bed shall comply with all applicable provisions of ASTM F1821–19ε1, Standard Consumer Safety Specification for Toddler Beds, approved June 1, 2019. The Director of the Federal Register approves the incorporation by reference listed in this section in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of this ASTM standard from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; phone: 610–832–9585; *www.astm.org.* You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Alberta E. Mills,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2019–23305 Filed 10–24–19; 8:45 am]

BILLING CODE 6355–01–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404, 408, and 416

[Docket No. SSA–2015–0006]

RIN 0960–AH78

Prohibiting Persons With Certain Criminal Convictions From Serving as Representative Payees; Correction

AGENCY: Social Security Administration.

ACTION: Correcting amendment.

SUMMARY: On February 15, 2019, we published final rules in the **Federal Register** to prohibit persons convicted of certain crimes from serving as representative payees under the Social Security Act (Act), as required by the Strengthening Protections for Social Security Beneficiaries Act of 2018. Those final rules inadvertently included two words in three places that should not have been there, and omitted one word in two sections of the rules. This document corrects the inadvertent inclusions and omissions in the final rules.

DATES: Effective October 25, 2019, and applicable beginning March 18, 2019.

FOR FURTHER INFORMATION CONTACT: Kevin Salamone, Office of Income Security Programs, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 966–0854. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION: We published final rules in the **Federal Register** on February 15, 2019 (83 FR 4323), that prohibit persons with certain criminal convictions from serving as representative payees. Those rules codified our responsibilities under the Strengthening Protections for Social Security Beneficiaries Act of 2018,[1] which prohibits the selection of certain representative payee applicants who have a specified felony conviction of committing, attempting, or conspiring to commit certain crimes. The law also requires us to review each individual currently serving as a representative payee (who does not meet one of the exceptions set out in the law) to determine whether the individual has been convicted of a specified crime, and continue to do so at least once every five years. The final rules inadvertently included the words ''or organization'' in §§ 404.2026, 408.626, and 416.626. They also inadvertently omitted the word ''individual'' from §§ 404.2024(a)(10) and 416.624(a)(10).

Although a representative payee may be an organization such as a social service agency, or an individual such as a parent, relative, or friend of the beneficiary, the final rules concerning a criminal background check and criminal history apply only to individuals applying to serve as representative payee and individuals currently serving as a representative payee. Accordingly, this correction removes the words ''or organization'' from the affected sections and clarifies our regulations. They also clarify in §§ 404.2024(a)(10) and 416.624(a)(10) that the criminal background check requirement applies to individual representative payee applicants.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; 96.006, Supplemental Security Income; and 96.020—Special Benefits for Certain World War II Veterans)

[1] Public Law 115–165, 132 Stat. 1257.

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

20 CFR Part 408

Administrative practice and procedure, Aged, Reporting and recordkeeping requirements, Social Security, Supplemental Security Income (SSI), Veterans.

20 CFR Part 416

Administrative practice and procedure, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

Andrew Saul,

Commissioner of Social Security.

Accordingly, 20 CFR parts 404, 408, and 416 are amended by making the following correcting amendments:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart U—Representative Payment

■ 1. The authority citation for subpart U of part 404 continues to read as follows:

Authority: Secs. 205(a), (j), and (k), and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), (j), and (k), and 902(a)(5)).

■ 2. Amend § 404.2024 by revising paragraph (a)(10) to read as follows:

§ 404.2024 How do we investigate a representative payee applicant?

* * * * *

(a) * * *

(10) Conduct a criminal background check on the individual payee applicant.

* * * * *

§ 404.2026 [Amended]

■ 3. Amend § 404.2026 to by removing the words ''or organization''.

PART 408—SPECIAL BENEFITS FOR CERTAIN WORLD WAR II VETERANS

Subpart F—Representative Payment

■ 4. The authority citation for subpart F of part 408 continues to read as follows:

Authority: Secs. 702(a)(5), 807, and 810 of the Social Security Act (42 U.S.C. 902(a)(5), 1007, and 1010).

§ 408.626 [Amended]

■ 5. Amend § 408.626 by removing the words ''or organization''.

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart F—Representative Payment

■ 6. The authority citation for subpart F of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1631(a)(2) and (d)(1) of the Social Security Act (42 U.S.C. 902(a)(5), 1383(a)(2) and (d)(1)).

■ 7. Amend § 416.624 by revising paragraph (a)(10) to read as follows:

§ 416.624 How do we investigate a representative payee applicant?

* * * * *

(a) * * *

(10) Conduct a criminal background check on the individual payee applicant.

* * * * *

§ 416.626 [Amended]

■ 8. Amend § 416.626 by removing the words ''or organization''.

[FR Doc. 2019–23235 Filed 10–24–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2019–N–2711]

Medical Devices; Orthopedic Devices; Classification of Orthopedic Surgical Instrumentation Designed for Osteochondral Implants With Press-Fit Fixation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 25, 2019. The classification was applicable on April 26, 2018.

FOR FURTHER INFORMATION CONTACT: Pooja Panigrahi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1449, Silver Spring, MD 20993–0002, 240–402–1090, *Pooja.Panigrahi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness for its intended use. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into the appropriate device class based on risk and the regulatory controls sufficient to provide reasonable assurance of safety and effectiveness.

FDA may classify a device through an accessory classification request under section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(6)), established by section 707 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52). The provision allows manufacturers or importers to request classification of an accessory distinct from another device upon written request. The classification is based upon the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request appropriate classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days announcing the classification.

Alternatively, under section 513(f)(6)(C), a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days announcing the classification.

II. Accessory Classification

On January 31, 2018, Cartiva, Inc., submitted a request for accessory classification of the Reusable Implantation Instruments for the Cartiva Synthetic Cartilage Implant. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

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

Therefore, on April 26, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 888.4505. We have named the generic type of device orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation, and it is identified as hand-held devices intended to manipulate bone and cartilage tissue or the implant for the positioning, alignment, defect creation, and placement of press-fit osteochondral implants that utilize no additional means of fixation (*e.g.,* suture fixation, adhesives). This type of device includes instruments specific to the geometry of the implant.

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

TABLE 1—ORTHOPEDIC SURGICAL INSTRUMENTATION DESIGNED FOR OSTEOCHONDRAL IMPLANTS WITH PRESS-FIT FIXATION RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Reprocessing validation and Labeling.
Implant malpositioning or migration	Validation of technical specifications and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order.

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine by order that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. We believe this may be such a device. The notice of intent to exempt the device from premarket notification requirements is published elsewhere in this issue of the **Federal Register**.

III. Analysis of Environmental Impact

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

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in the guidance document ''Medical Device Accessories—Describing Accessories and Classification Pathways'' have been approved under OMB control number 0910–0823; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 820, regarding current good manufacturing practices, have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 2. Add § 888.4505 to subpart E to read as follows:

§ 888.4505 Orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation.

(a) *Identification.* Orthopedic surgical instruments designed for osteochondral implants with press-fit fixation are hand-held devices intended to manipulate bone and cartilage tissue or the implant for the positioning, alignment, defect creation, and placement of press-fit osteochondral implants that utilize no additional means of fixation (*e.g.,* suture fixation, adhesives). This type of device includes instruments specific to the geometry of the implant.

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

(1) Technical specifications regarding geometry of the instruments must be specified and validated to demonstrate that the instruments can safely position and place the implant.

(2) The patient contacting components of the device must be demonstrated to be biocompatible.

(3) Labeling must include:

(i) Identification of implant(s) and instruments which have been validated for use together; and

(ii) Validated methods and instructions for reprocessing any reusable parts.

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23307 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2019–N–2675]

Medical Devices; Physical Medicine Therapeutic Devices; Classification of the Internal Therapeutic Massager

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the internal therapeutic massager into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the internal therapeutic massager's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe

this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective October 25, 2019. The classification was applicable on November 20, 2012.

FOR FURTHER INFORMATION CONTACT: Vivek Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2668, Silver Spring, MD, 20993–0002, 301–796–1136, *Vivek.Pinto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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

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

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

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

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

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

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

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

II. De Novo Classification

For this device, FDA issued an order on July 27, 2010, finding the American Health Insurance Plans (AHIP) Internal Trigger Point Wand not substantially equivalent to a predicate not subject to premarket approval. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On August 20, 2010, National Center for Pelvic Pain Research Devices, Inc. submitted a request for De Novo classification of the AHIP Internal Trigger Point Wand. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

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

Therefore, on November 20, 2012, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 890.5670. We have named the generic type of device internal therapeutic massager, and it is identified as a hand-held prescription device intended for medical purposes to manually provide direct pressure applied to localized areas of pain or tenderness in the myofascial tissue associated with chronic pelvic pain syndromes. The device is inserted rectally or vaginally and provides quantitative feedback to the user of the applied force to the target tissue.

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

TABLE 1—INTERNAL THERAPEUTIC MASSAGER RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation, and Labeling.
Tissue bruising, abrasion or tearing	Non-clinical performance testing, and Labeling.

TABLE 1—INTERNAL THERAPEUTIC MASSAGER RISKS AND MITIGATION MEASURES—Continued

Identified risks	Mitigation measures
Microbial contamination from reusable components	Labeling.
Vaginal/rectal cross-contamination	Labeling.
Overstretching/weakness of the anal sphincter and vagina	Non-clinical performance testing, and Labeling.
Mechanical failure during use	Non-clinical performance testing.
User error	Labeling.
Electrical shock	Electrical safety testing, and Labeling.
Electromagnetic incompatibility	Electromagnetic compatibility testing, and Labeling.
Software failure	Software verification, validation, and hazard analysis.

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

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

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine by order that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. We believe this may be such a device. The notice of intent to exempt the device from premarket notification requirements is published elsewhere in this issue of the **Federal Register**.

III. Analysis of Environmental Impact

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

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844; the collections of information in part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. Add an authority citation for part 890 to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 2. Add § 890.5670 to subpart F to read as follows:

§ 890.5670 Internal therapeutic massager.

(a) *Identification.* A hand-held internal therapeutic massager device is a prescription device intended for medical purposes to manually provide direct pressure applied to localized areas of pain or tenderness in the myofascial tissue associated with chronic pelvic pain syndromes. The device is inserted rectally or vaginally and provides quantitative feedback to the user of the applied force to the target tissue.

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

(1) Labeling must include adequate directions for use.

(2) Non-clinical performance testing must demonstrate electromagnetic compatibility (EMC), electrical safety and mechanical safety.

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

(i) Mechanical durability; and

(ii) Accuracy of the feedback mechanism.

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

(5) The patient-contacting components of the device must be demonstrated to be biocompatible.

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23304 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–507]

Schedules of Controlled Substances: Placement of Cyclopropyl Fentanyl, Methoxyacetyl fentanyl, ortho-Fluorofentanyl, and para-Fluorobutyryl Fentanyl in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final amendment; final order.

SUMMARY: With the issuance of this final order, the Acting Administrator of the Drug Enforcement Administration

maintains the placement of the substances cyclopropyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopropanecarboxamide), methoxyacetyl fentanyl (2-methoxy-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide), *ortho*-fluorofentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide), and *para*-fluorobutyryl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide), including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, in schedule I of the Controlled Substances Act. This scheduling action discharges the United States' obligations under the Single Convention on Narcotic Drugs (1961). This action continues to impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle, cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl.

DATES: Effective October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

Section 201(d)(1) of the Controlled Substances Act (CSA) (21 U.S.C. 811(d)(1)) states that, if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by [section 201(a) (21 U.S.C. 811(a)] or section [202(b) (21 U.S.C. 812(b)) of the Act] and without regard to the procedures prescribed by [section 201 (a) and (b) (21 U.S.C. 811(a) and (b)].'' If a substance is added to one of the schedules of the Single Convention on Narcotic Drugs (1961), then, in accordance with article 3, paragraph 7 of the Convention, as a signatory Member State, the United States is obligated to control the substance under its national drug control legislation, the CSA. The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100.

Background

On May 23, 2019, the Secretary-General of the United Nations send a letter to the Secretary of State of the United States advising him that during the 62nd session of the Commission on Narcotic Drugs, cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl were added to Schedule I of the Single Convention on Narcotic Drugs (1961). This letter was prompted by a decision at the 62nd session of the Commission on Narcotic Drugs in March 2019 to schedule cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl under Schedule I of the Single Convention on Narcotic Drugs. As a signatory Member State to the Single Convention on Narcotic Drugs, the United States is obligated to control cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl under its national drug control legislation, the CSA, in the schedule deemed most appropriate to carry out its international obligations. 21 U.S.C. 811(d)(1).

Cyclopropyl Fentanyl, Methoxyacetyl Fentanyl, *ortho*-Fluorofentanyl, and *para*-Fluorobutyryl Fentanyl

Cyclopropyl fentanyl (83 FR 469, January 4, 2018), methoxyacetyl fentanyl and *ortho*-fluorofentanyl (82 FR 49504, October 26, 2017), and *para*-fluorobutyryl fentanyl (83 FR 4580, February 1, 2018) were temporarily controlled in schedule I of the CSA upon finding that they pose an imminent hazard to the public safety. These substances share pharmacological profiles similar to morphine, fentanyl, and other synthetic opioids which act as μ-opioid receptor agonists. For this reason, cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl are abused for their opioid-like effects. Law enforcement and public health reports demonstrate the illicit use and distribution of these substances, which are similar to that of heroin and prescription opioid analgesics.

Cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl were identified in law enforcement encounters in the United States. The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by other federal, state and local forensic laboratories across the country. According to NFLIS,[1] cyclopropyl fentanyl (first reported in 2016) was identified in 2,461 exhibits submitted to forensic laboratories, methoxyacetyl fentanyl (first reported in 2017) was identified in 1,718 exhibits, *ortho*-fluorofentanyl (first reported in 2016) was identified in 13 exhibits, and *para*-fluorobutyryl fentanyl (first reported in 2015) was identified in 309 exhibits.

The DEA is not aware of any claims or any medical or scientific literature suggesting that cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, or *para*-fluorobutyryl fentanyl have a currently accepted medical use in treatment in the United States. In addition, the Department of Health and Human Services (HHS) advised the DEA, by letters dated September 6, 2017 (cyclopropyl fentanyl), July 14, 2017 (methoxyacetyl fentanyl), June 9, 2017 (*ortho*-fluorofentanyl), and November 8, 2017 (*para*-fluorobutyryl fentanyl) that there were no investigational new drug applications or approved new drug applications for these substances.

The DEA requested that HHS conduct a scientific and medical evaluation and a scheduling recommendation for methoxyacetyl fentanyl and *ortho*-fluorofentanyl (by letter dated April 18, 2018) and cyclopropyl fentanyl and *para*-fluorobutyryl fentanyl (by letter dated November 5, 2018). Regardless of these requests and any potential responses from HHS, the DEA is not required under 21 U.S.C. 811(d)(1) to make any findings otherwise required by 21 U.S.C. 811(a) or 812(b), and is not required to follow the procedures prescribed by 21 U.S.C. 811(a) and (b). The Acting Administrator advised HHS, by letter dated September 6, 2019, that the DEA no longer requires scientific and medical evaluations and scheduling recommendations for cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl. These evaluations are no longer required due to the placement of these substances in Schedule I of the Single Convention on Narcotic Drugs (1961) in March 2019. Therefore, consistent with the framework of 21 U.S.C. 811(d), the DEA concludes that cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl have no currently accepted medical use in treatment in the United States and are most

[1] NFLIS was queried on June 7, 2019. Data are still being collected for January 2019—June 2019 due to the normal lag period for labs reporting to NFLIS.

appropriately placed in schedule I of the CSA, the same schedule in which they currently reside. Further, while the DEA temporarily scheduled these substances under 21 CFR 1308.11(h), a paragraph reserved for the temporary listing of substances subject to emergency scheduling, this order moves these substances to 21 CFR 1308.11(b). As explained above, because control is required under the Single Convention on Narcotic Drugs (1961), the DEA will not be initiating regular rulemaking proceedings to schedule these substances pursuant to 21 U.S.C. 811(a).

Conclusion

In order to meet the United States' obligations under the Single Convention on Narcotic Drugs (1961) and because cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl have no currently accepted medical use in treatment in the United States, the Acting Administrator of the DEA has determined that these substances should remain in schedule I of the CSA.

Requirements for Handling

Cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl have been controlled as schedule I controlled substances since January 4, 2018, October 26, 2017, October 26, 2017, and February 1, 2018, respectively. With publication of the final order contained in this document, cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl remain subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, importation, exportation, engagement in research, conduct of instructional activities, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, imports, exports, engages in research or conducts instructional activities with, or possesses), or who desires to handle, cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl must be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl are subject to schedule I security requirements and must be handled and stored in accordance with 21 CFR 1301.71–1301.93.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl must be in compliance with 21 U.S.C. 825 and 958(e), and must be in accordance with 21 CFR part 1302.

5. *Quota.* A quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 is required in order to manufacture cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl.

6. *Inventory.* Every DEA registrant who possesses any quantity of cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl was required to keep an inventory of all stocks of these substances on hand as of January 4, 2018, October 26, 2017, October 26, 2017, and February 1, 2018, respectively, pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* DEA registrants must maintain records and submit reports with respect to cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl pursuant to 21 U.S.C. 827 and 958(e), and in accordance with 21 CFR parts 1304, 1312, and 1317.

8. *Order Forms.* All DEA registrants who distribute cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305.

9. *Importation and Exportation.* All importation and exportation of cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl must be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312.

10. *Liability.* Any activity involving cyclopropyl fentanyl, methoxyacetyl fentanyl, *ortho*-fluorofentanyl, and *para*-fluorobutyryl fentanyl not authorized by, or in violation of the CSA, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Order 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

This action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and the principles reaffirmed in Executive Order 13563 (Improving Regulation and Regulatory Review), and, accordingly, this action has not been reviewed by the Office of Management and Budget (OMB).

This order is not an Executive Order 13771 regulatory action.

Executive Order 12988, Civil Justice Reform

This action meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This action does not have federalism implications warranting the application of Executive Order 13132. This action 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.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications warranting the application of Executive Order 13175. The action 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.

Administrative Procedure Act

The CSA provides for an expedited scheduling action where control is required by the United States obligations under international treaties, conventions, or protocols. 21 U.S.C. 811(d)(1). If control is required pursuant to such international treaty, convention, or protocol, the Attorney General must issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings or procedures otherwise required for scheduling actions. *Id.*

To the extent that 21 U.S.C. 811(d)(1) directs that if control is required by the United States' obligations under international treaties, conventions, or protocols in effect on October 27, 1970, scheduling actions shall be issued by order (as compared to scheduling pursuant to 21 U.S.C. 811(a) by rule), the DEA believes that the notice and comment requirements of section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553, do not apply to this scheduling action. In the alternative, even if this action does constitute ''rule making'' under 5 U.S.C. 551(5), this

action is exempt from the notice and comment requirements of 5 U.S.C. 553 pursuant to 21 U.S.C. 553(a)(1) as an action involving a foreign affairs function of the United States given that this action is being done in accordance with 21 U.S.C. 811(d)(1)'s requirement that the United States comply with its obligations under the specified international agreements.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) applies to rules that are subject to notice and comment under section 553(b) of the APA or any other law. As explained above, the CSA exempts this final order from notice and comment. Consequently, the RFA does not apply to this action.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. 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.

Congressional Review Act

This action is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This order will not result in: ''an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or 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.'' However, pursuant to the CRA, the DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11:

■ a. Redesignate paragraphs (b)(51) through (b)(66) as (b)(55) through (70);

■ b. Redesignate paragraphs (b)(41) through (b)(50) as (b)(43) through (52);

■ c. Redesignate paragraphs (b)(22) through (40) as (b)(23) through (41);

■ d. Add new paragraphs (b)(22), (42), (53), and (54); and

■ e. Remove and reserve paragraphs (h)(19), (21), (22), and (24).

The additions read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(22) Cyclopropyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopropanecarboxamide) 9845

* * * * *

(42) Methoxyacetyl fentanyl (2-methoxy-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide) 9825

* * * * *

(53) *ortho*-Fluorofentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide); other name: 2-fluorofentanyl) 9816

(54) *para*-Fluorobutyryl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide) 9823

* * * * *

Dated: October 19, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019–23348 Filed 10–24–19; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 314

[Docket ID: DOD–2019–OS–0041]

RIN 0790–AK60

Defense Advanced Research Projects Agency, Privacy Act of 1974

AGENCY: Defense Advanced Research Projects Agency, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: This final rule removes DoD's regulation concerning the Defense Advanced Research Projects Agency (DARPA) Privacy Program. On April 11, 2019, the DoD published a revised DoD-level Privacy Program rule, which contains the necessary information for an agency-wide Privacy Program regulation under the Privacy Act and now serves as the single Privacy Program rule for the Department. That revised Privacy Program rule also includes all DoD component exemption rules. Therefore, this regulation is now unnecessary and may be removed from the CFR.

DATES: This rule is effective on October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Brian Eshenbrenner at 703–526–6631.

SUPPLEMENTARY INFORMATION: DoD now has a single DoD-level Privacy Program rule at 32 CFR part 310 (84 FR 14728) that contains all the codified information required for the Department. The DARPA Privacy Act Program regulation at 32 CFR part 314, last updated on November 14, 1991 (56 FR 57802), is no longer required and can be removed.

It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest because it is based on the removal of policies and procedures that are either now reflected in another CFR part, 32 CFR part 310, or are publically available on the Department's website. To the extent that DARPA internal guidance concerning the implementation of the Privacy Act within DARPA is necessary, it will continue to be published in DARPA Instruction 78, ''Privacy and Civil Liberties,'' and referenced under DARPA's respective Privacy and Civil Liberties Programs at *https://www.darpa.mil.*

This rule is one of 20 separate component Privacy rules. With the finalization of the DoD-level Privacy rule at 32 CFR part 310, the Department eliminated the need for this component Privacy rule, thereby reducing costs to the public as explained in the preamble of the DoD-level Privacy rule published on April 11, 2019, at 84 FR 14728–14811.

This rule is not significant under Executive Order (E.O.) 12866, ''Regulatory Planning and Review.'' Therefore, E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' does not apply.

List of Subjects in 32 CFR Part 314

Privacy.

PART 314—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 314 is removed.

Dated: October 22, 2019.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–23311 Filed 10–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ56

Center for Innovation for Care and Payment

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final a proposed rule amending its regulations that govern VA health care. This final rule establishes parameters and authority for the new Center for Innovation for Care and Payment in its conduct of pilot programs designed to develop innovative approaches to testing payment and service delivery models to reduce expenditures while preserving or enhancing the quality of care furnished by VA.

DATES: *Effective Date:* This rule is effective November 25, 2019.

FOR FURTHER INFORMATION CONTACT: Michael Akinyele, VA Chief Innovation Officer and Executive Director (Acting), VA Innovation Center (VIC) (008E), 810 Vermont Ave NW, Washington, DC 20420. *Michael.Akinyele@va.gov.* (202) 461–7271. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On June 6, 2018, section 152 of Public Law 115–182, the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018, or the VA MISSION Act of 2018, amended title 38 of the United States Code (U.S.C.) by adding a new section 1703E, Center for Innovation for Care and Payment. This final rule implements this new authority and establishes the parameters and authority for the new Center for Innovation for Care and Payment (the Center) in its conduct of pilot programs designed to develop innovative approaches to testing payment and service delivery models to reduce expenditures while preserving or enhancing the quality of care furnished by VA.

VA published a proposed rule on the Center on July 29, 2019. 84 FR 36507. The public comment period closed on August 28, 2019. In response to this proposed rule, VA received multiple comments. Several of the comments expressed support for the rule in whole or in part. One comment supported the proposed ability to expand pilot program duration for up to an additional 5 years. The comment suggested that an extended pilot program duration would afford clinicians greater opportunity to improve care and obtain actionable data beyond the initial pilot program duration. One comment supported many elements of the proposed rule: VA's definition of the term reduction in expenditures; the ability to waive applicable regulations along with provisions of law; and VA's ability to extend and expand successful pilot programs. We appreciate the comments' support and make no changes to these provisions.

Many of the comments addressed issues related to implementation or ideas for specific pilot programs; because these are generally outside the scope of the rulemaking, we make no changes based on these comments. However, we summarize these comments below and address them as appropriate.

Several comments made recommendations on whom VA should consult in developing pilot programs. One comment supported VA's intent to consult with Federal agencies and medical and health experts. The comment encouraged VA to solicit input from professional associations and clinicians to ensure VA obtains a broad swath of input, guidance, and suggestions on innovations and programmatic priorities. The comment further encouraged VA to prioritize health promotion and disease prevention models that focus on keeping people healthy. One comment suggested that the inclusion of nurse practitioners (NP) in VA's consultation with relevant Federal agencies and clinical and analytical experts would be important in developing effective care models. One comment urged VA to collaborate with veterans organizations in local communities to ensure that veterans receive proper notice and information regarding pilot programs. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals. We make no changes based on these comments.

Other comments made recommendations as to what types of pilot programs VA should pursue. One comment encouraged VA to consider models that enhance community design to promote safe physical activity and active forms of transportation for individuals and populations of all ages and abilities. The comment also recommended VA consider the development of a model that directs patients with musculoskeletal disorders to physical therapists for primary assessment in primary care. The comment also recommended that VA consider how it may integrate public information and performance metrics to assess the quality, timeliness, and patient satisfaction of care and services furnished. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals. We make no changes based on this comment.

One comment supported the use of evidence-based health care models as necessary to make improvements to VA's health care system. The comment stated that finding the right health care model is essential in streamlining veterans' care. The comment encouraged VA to be strategic in creating pilot studies to provide efficient, cost-effective care without sacrificing quality of care. The comment recommended VA health care delivery models adhere to proper guideline requirements for recommended screenings and health promotion initiatives. The comment also encouraged the prioritization of care models addressing common health conditions unique to veterans, such as mental health or substance abuse disorders. The comment also recommended addressing barriers to care including better payment systems with timely reimbursement to non-VA health care providers and competency training for providers to ensure culturally competent care. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals; however, because these comments make no recommendations regarding the specific provisions of this rule, which lays out the parameters of the Center, we make no changes based on these comments.

One comment supported the creation of the Center and noted that it looked forward to having NPs working with VA on the development of new pilot programs. The comment stated than an overarching goal should be to support and create models providing equal opportunity for participation of clinicians and their patients. The comment suggested including NPs as full participants in pilot programs as one way to increase participation. The comment noted that patient outcomes are improved and cost savings are realized when NPs are utilized to the fullest extent of their educational and clinical training. The comment noted this has been demonstrated in a number of models within the Center for Medicare and Medicaid Innovation. The comment suggested that including NPs as full participants would help VA enhance the quality of care provided to veterans while also reducing

expenditures. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals. We make no changes based on this comment.

One comment was broadly supportive of the proposed rule. The comment recommended a specific focus on modernizing drug pricing to allow for greater adoption of more flexible pricing arrangements, greater value for patients, and an improved standard of care. The comment encouraged a shift from rebated and volume discount pricing arrangements to an outcomes/value-based flexible pricing arrangement. The comment also encouraged VA to continue to ensure that existing arrangements for value-based health care are not impacted by this rulemaking. The comment recommended VA assess the ability to increase the amount of value-based health care contracting opportunities within VA systems and encouraged further rulemaking in this area. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals. We make no changes based on this comment.

One comment recommended leveraging existing partnerships to design and test innovations in telehealth, data exchange, care transitions, and other areas. The comment noted that comparative effectiveness studies could identify cost and quality outliers, leading to a mutually beneficial exchange of best practices between VA and community-based providers. We appreciate this input but make no changes based on this comment, which makes no recommendations regarding provisions of the proposed rule.

One comment stated that it believed this new Center has the potential to facilitate additional opportunities to more fully engage massage therapy within veterans' health care, such as providing test cohorts of community-based massage therapists, determining how well massage therapists are receiving provider referrals for massage therapy, assessing outcomes following a treatment cycle, and providing important measurements to add to the research base on massage efficacy and cost-effectiveness for various conditions. The comment also noted the efficacy of massage therapy as a non-pharmacologic approach to pain management, and its recognition in guidelines for non-pharmacologic opioid alternatives by the Attorney General of West Virginia. We appreciate the comment's perspective regarding potential pilot programs but make no changes based on this comment.

One comment recommended VA consider, in developing pilot programs, recommendations made by the Commission on Care established by section 202 of the Veterans Access, Choice, and Accountability Act of 2014 (Pub. L. 113–146) that have not yet been acted upon by Congress or VA. Other possible pilot programs recommended by the comment included VA prioritizing treatment for service-connected conditions that are common among veterans, including posttraumatic stress disorder and mental health concerns; modifying VA's personnel system to allow for improved flexibility to respond to market conditions related to compensation, benefits, and recruitment; making VA the secondary payer for all non-service-connected health care in the community; and fully utilizing nurse practitioners and physician assistants to improve access to primary care, enhance quality, and reduce expenditures. We appreciate these recommendations regarding specific pilot programs and will take them under advisement. However, because these deal with specific pilot programs, and not with VA's general authority to operate the Center addressed in this rulemaking, we make no changes based on this comment.

Some comments discussed issues generally raised by other parts of the rule. One comment generally supported the use of patient health care experience tools in determining patient satisfaction but expressed concern that some of these tools are outdated and do not recognize NPs. The comment stated that survey tools omitting NPs would fail to provide accurate health care delivery information. The comment encouraged VA to accurately capture patient satisfaction data by developing updated patient satisfaction tools that include NPs. We appreciate these recommendations and will take them into consideration when developing specific pilot proposals. We make no changes based on this comment.

One comment urged VA to actively seek and fill as many of the new leadership positions within the Center as possible with outside candidates who have experience with designing and creating proven innovative health care delivery solutions and can bring that experience to the Center and to VA. The comment also urged VA to select internal candidates for the Center's leadership team who can best foster a collaborative environment that inspires effective innovation to enhance how VA delivers health care services to veterans. We make no changes based on this comment.

One comment recommended VA use the same terminology and definitions used by non-VA providers. The comment did not identify any specific terms it believed were inconsistent with industry standards; indeed, it recognized that many of the terms VA proposed are well established and consensus-based definitions. The comment recognized that it may be necessary to use a different definition but urged VA to start with the presumption of aligning terms and definitions. As we explained in our proposed rule, we believe the definitions we proposed are consistent with how these terms are used in the industry, and to the extent there is any variation, we believe our definitions are broader to allow for maximal flexibility in designing and operating pilot programs. We make no changes based on this comment.

One comment proposed VA allow non-VA providers and other stakeholders who are not affiliated with VA to propose pilot ideas. The comment recommended using the Center for Medicare and Medicaid Innovation's process for soliciting ideas as a starting point. The comment recognized that a more open process may take more time but could provide a greater breadth and depth of innovative pilot program concepts. We appreciate this recommendation and anticipate development of a system that would permit this type of voluntary input. We make no changes based on this comment.

Two comments expressed differing interpretations of provisions in the proposed rule concerning the operational independence of the Center. One comment supported the Center's operational independence from VA's three administrations because this would grant it the appropriate access and decision-making authority to work across the entire VA system to re-imagine care delivery, break and eliminate internal systemic barriers, create efficiencies, and improve care for veterans. Another comment, however, supported the Center being operationally independent from VA while also collaborating with VA. These comments indicate this language was unclear, so VA is revising paragraph (a) to remove the reference to and definition of operational independence. VA will retain the language in the proposed rule from paragraph (a)(3), now redesignated as paragraph (a)(2), that the Center will not operate within any specific administration. This should emphasize the Center's role within VA,

but as an organization that can break and eliminate internal barriers, create efficiencies, and improve care for veterans. We further clarify that the Center is part of VA and acts at the direction of the Secretary, so it is not ''independent'' from VA; in the proposed rule, we stated that the Center will report through the Office of the Secretary of Veterans Affairs and ultimately the President of the United States and does not have the unilateral authority to execute pilot programs. (84 FR 36507, 36508.)

Effect of Rulemaking

The Code of Federal Regulations, as revised by this rulemaking, represents the exclusive legal authority on this subject. No contrary rules or procedures will be authorized. All VA guidance will be read to conform with this rulemaking if possible or, if not possible, such guidance will be superseded by this rulemaking.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule adopts regulations that are largely procedural, and will not, without Congressional approval of a pilot program proposal from VA, result in any change in benefits or services by themselves. Thus, this final rule will not have a significant economic impact on qualifying non-VA entities or providers. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866, 13563 and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The Office of Information and Regulatory Affairs has determined that this rulemaking is a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at *http://www.regulations.gov,* usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at *http://www.va.gov/orpm* by following the link for VA Regulations Published from FY 2004 through FYTD. This final rule is not subject to the requirements of Executive Order 13771 because this final rule is expected to result in no more than *de minimis* costs.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are as follows: 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.016, Veterans State Hospital Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; and 64.022, Veterans Home Based Primary Care.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Signing Authority

The Secretary of Veterans Affairs approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Pamela Powers, Chief of Staff, Department of Veterans Affairs, approved this document on October 4, 2019, for publication.

Dated: October 23, 2019.

Michael P. Shores,

Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set forth in the preamble, we amend 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 is amended by adding an entry for § 17.450 in numerical order to read in part as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

* * * * *

Section 17.450 is also issued under 38 U.S.C. 1703E.

* * * * *

■ 2. Add an undesignated center heading and § 17.450 to read as follows.

Center for Innovation for Care and Payment

§ 17.450 Center for Innovation for Care and Payment.

(a) *Purpose and organization.* The purpose of this section is to establish procedures for the Center for Innovation for Care and Payment.

(1) The Center for Innovation for Care and Payment will be responsible for working across VA to carry out pilot programs to develop innovative approaches to testing payment and service delivery models to reduce expenditures while preserving or enhancing the quality of care furnished by VA.

(2) The Center for Innovation for Care and Payment will not operate within any specific administration but will operate in VA's corporate portfolio to ensure the limited number of concurrent pilot programs under this section are

not redundant of or conflicted by ongoing innovation efforts within any specific administration.

(b) *Definitions.* The following definitions apply to this section.

Access refers to entry into or use of VA services.

Patient satisfaction of care and services refers to patients' rating of their experiences of care and services and as further defined in a pilot program proposal.

Payment models refer to the types of payment, reimbursement, or incentives that VA deems appropriate for advancing the health and well-being of beneficiaries.

Pilot program refers to a pilot program conducted under this section.

Quality enhancement refers to improvement or improvements in such factors as clinical quality, beneficiary-level outcomes, and functional status as documented through improvements in measurement data from a reliable and valid source, and as further defined in a pilot program proposal.

Quality preservation refers to the maintenance of such factors as clinical quality, beneficiary-level outcomes, and functional status as documented through maintenance of measurement data from an evidence-based source, and as further defined in a pilot program proposal.

Reduction in expenditure refers to, but is not limited to, cost stabilization, cost avoidance, or decreases in long- or short-term spending, and as further defined in a pilot program proposal. NOTE: VA will also consider the proposal's potential impact on expenditures for other related Federal programs; however, this potential impact will not count against the limitation in paragraph (d)(2) of this section.

Service delivery models refer to all methods or programs for furnishing care or services.

(c) *Geographic locations.* VA will make decisions regarding the location of each pilot program based upon the appropriateness of testing a specific model in a specific area while taking efforts to ensure that pilot programs are operated in geographically diverse areas of the country. VA will include in its proposal to Congress and publish a document in the **Federal Register** identifying the geographic locations proposed for each pilot program, the rationale for those selections, and how VA believes the selected locations will address deficits in care for a defined population.

(d) *Limitations.* In carrying out pilot programs under this section, VA will not:

(1) Actively operate more than 10 pilot programs at the same time; and

(2) Consistent with 38 U.S.C. 1703E(d), obligate more than $50 million in any fiscal year in the conduct of the pilot programs (including all administrative and overhead costs, such as measurement, evaluation, and expenses to implement the pilot programs themselves) operated under this section, unless VA determines it to be necessary and submits a report to the appropriate Committees of Congress that sets forth the amount of, and justification for, the additional expenditure.

(e) *Waiver of authorities.* In carrying out pilot programs under this section, VA may waive statutory provisions by adding to or removing from statutory text in subchapters I, II, and III of chapter 17, title 38, U.S.C., upon Congressional approval, including waiving any provisions of law in any provision codified in or included as a note to any section in subchapter I, II, or III of chapter 17, title 38.

(1) Upon Congressional approval of the waiver of a provision of law under this section, VA will also deem waived any applicable provision of regulation implementing such law as identified in VA's pilot program proposal.

(2) VA will publish a document in the **Federal Register** providing information about, and seeking comment on, each proposed pilot program upon its submission of a proposal to Congress for approval. VA will publish a document in the **Federal Register** to inform the public of any pilot programs that have been approved by Congress.

(f) *Notice of eligibility.* VA will take reasonable actions to provide direct notice to veterans eligible to participate in a pilot program operated under this section and will provide general notice to other individuals eligible to participate in a pilot program. VA will announce its methods of providing notice to veterans, the public, and other individuals eligible to participate through the document it publishes in the **Federal Register** for each proposed and approved pilot program.

(g) *Evaluation and reporting.* VA will evaluate each pilot program operated under this section and report its findings. Evaluations may be based on quantitative data, qualitative data, or both. Whenever appropriate, evaluations will include a survey of participants or beneficiaries to determine their satisfaction with the pilot program. VA will make the evaluation results available to the public on the VA Innovation Center website on the schedule identified in VA's proposal for the pilot program.

(h) *Expansion of pilot programs.* VA may expand a pilot program consistent with this paragraph (h).

(1) VA may expand the scope or duration of a pilot program if, based on an analysis of the data developed pursuant to paragraph (g) of this section for the pilot program, VA expects the pilot program to reduce spending without reducing the quality of care or improve the quality of patient care without increasing spending. Expansion may only occur if VA determines that expansion would not deny or limit the coverage or provision of benefits for individuals under 38 U.S.C. chapter 17. Expansion of a pilot program may not occur until 60 days after VA has published a document in the **Federal Register** and submitted an interim report to Congress stating its intent to expand a pilot program.

(2) VA may expand the scope of a pilot program by modifying, among other elements of a pilot program, the range of services provided, the qualifying conditions covered, the geographic location of the pilot program, or the population of eligible participants in a manner that increases participation in or benefits under a pilot program.

(3) In general, pilot programs are limited to 5 years of operation. VA may extend the duration of a pilot program by up to an additional 5 years of operation. Any pilot program extended beyond its initial 5-year period must continue to comply with the provisions of this section regarding evaluation and reporting under paragraph (g) of this section.

(i) *Modification of pilot programs.* The Secretary may modify elements of a pilot program in a manner that is consistent with the parameters of the Congressional approval of the waiver described in paragraph (e) of this section. Such modification does not require a submission to Congress for approval under paragraph (e) of this section.

(j) *Termination of pilot programs.* If VA determines that a pilot program is not producing quality enhancement or quality preservation, or is not resulting in the reduction of expenditures, and that it is not possible or advisable to modify the pilot program either through submission of a new waiver request under paragraph (e) of this section or through modification under paragraph (i) of this section, VA will terminate the pilot program within 30 days of submitting an interim report to Congress that states such determination. VA will also publish a document in the **Federal**

Register regarding the pilot program's termination.

[FR Doc. 2019–23484 Filed 10–24–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0300; FRL–9999–58]

Fenbuconazole; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenbuconazole in or on tea. Dow Agrosciences, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 25, 2019. Objections and requests for hearings must be received on or before December 24, 2019 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–2018–0300, 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: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2018–0300 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before December 24, 2019. 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–2018–0300, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 24, 2018 (83 FR 34968) (FRL–9980–31), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E8678) by Dow Agrosciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.480 be amended by establishing tolerances for residues of the fungicide fenbuconazole, in or on the raw agricultural commodities tea, dried at 10 parts per million (ppm); and tea, instant at 10 ppm. That document referenced a summary of the petition prepared by Dow Agrosciences, LLC, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

After the publication of the notice of filing in the **Federal Register**, Dow Agrosciences, LLC requested that its requested tolerance for residues on tea be established at 30 ppm in/on tea, dried and tea, instant based on additional magnitude of the residue studies conducted in 2016 and 2017.

Based upon the data reviewed by the Food Safety Commission of Japan, EPA is establishing tolerances for tea, dried and tea, instant at 30 ppm. The reason for these changes are explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in

residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

A. Toxicological Profile

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

Subchronic and chronic feeding studies were conducted in the rat, mouse, and dog. The liver was the main target of toxicity in all three species. At lower dose levels in the subchronic studies, there were changes in liver histopathology, predominantly hepatocellular hypertrophy, along with increased liver weight. In the absence of other findings, these effects appeared to be adaptive liver changes, but at higher dose levels, increased levels of enzymes indicative of liver damage were observed (alkaline phosphatase or ALK; serum glutamic-pyruvic transaminase or SGPT; and serum glutamic-oxaloacetic transaminase or SGOT). Increased hepatocellular vacuolization was observed at the higher dose levels as well, and in mice after subchronic exposure, hepatocellular necrosis was observed with a low incidence at the highest dose. In the rat after subchronic exposure, the thyroid was a secondary target organ with increased follicular cell size. In the chronic studies, liver effects were observed (including hepatocellular hypertrophy and vacuolization, changes in liver enzymes, and increased liver weights), as well as decreased body weight gains in all three species. Again, in the chronic rat study, the thyroid was a secondary target with increased thyroid and parathyroid weights and thyroid follicular cell hypertrophy. In addition, thyroid hormones were affected, with increased mean T4 (thyroxine) and decreased TSH (thyroid stimulating hormone) being observed in the high-dose rats near the end of the study. In the chronic dog study, kidney and adrenal weights were also increased.

In the rat and rabbit developmental toxicity studies and the rat two-generation study, all effects in the pups occurred in the presence of maternal toxicity, including changes in body weight in rats and decreased food consumption and clinical signs in rabbits. Developmental effects included increased post-implantation loss and decreased fetuses per dam in the rat developmental study; increased early resorptions in the rabbit developmental study; and decreased mean pup body weight, increased number of stillborn pups, decreased number of total offspring delivered, and decreased viability index of pups in the two-generation study in rats. No increased qualitative or quantitative susceptibility was observed in any of the studies. There was no evidence of neurotoxicity in any of the studies available in the toxicology database.

Fenbuconazole is classified as a ''Group C,'' or possible human carcinogen, based on an increased incidence of liver tumors in male and female mice and thyroid tumors in male rats. A cancer potency factor has been used to estimate potential cancer risk associated with fenbuconazole uses.

Specific information on the studies received and referenced in this section and the nature of the adverse effects caused by fenbuconazole, as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled ''Fenbuconazole: Human Health Risk Assessment for Proposed Use on Imported Tea,'' on pages 23–30 in docket ID number EPA–HQ–OPP–2018–0300.

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for fenbuconazole used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FENBUCONAZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age) ...	NOAEL = 30 mg/kg/day ..... UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.3 mg/kg/day .... aPAD = 0.3 mg/kg/day	*Developmental Toxicity (Rat) Developmental* LOAEL = 75 mg/kg/day based on increased resorption and decreased live fetuses per dam.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FENBUCONAZOLE FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (General population including infants and children).	An endpoint for acute dietary (general population) exposures was not selected. An appropriate dose and endpoint were not identified for this population group.		
Chronic dietary (All populations)	NOAEL = 3 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.03 mg/kg/day cPAD = 0.03 mg/kg/day	*Combined Chronic Toxicity/ Carcinogenicity (Rat)* LOAEL = 30.6 mg/kg/day based on decreased body weight gain, increased thyroid weight, and histopathogical lesions in the liver and thyroid gland.
Cancer (Oral, dermal, inhalation)	Classification: Group C, possible human carcinogen. This classification is based on increased incidence of hepatocellular adenomas and carcinomas in male and female mice and thyroid follicular adenomas and combined adenomas/carcinomas in male rats. Quantification of risk was derived using combined hepatocellular adenomas/carcinomas in female mice. The upper bound estimate of unit risk, Q_1* (mg/kg/day)$^{-1}$ is 3.59×10^{-3} in human equivalents. (TXR #0011894; CPRC; 4/15/1996)		

FQPA SF = Food Quality Protection Act Safety Factor. LOC = level of concern. mg/kg/day = milligram/kilogram/day. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fenbuconazole, EPA considered exposure under the petitioned-for tolerances as well as all existing fenbuconazole tolerances in 40 CFR 180.480. EPA assessed dietary exposures from fenbuconazole in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Although no endpoints of concern were identified for the general population including infants and children, such effects were identified for fenbuconazole for females 13–49 years old. In estimating acute dietary exposure, EPA used 2003–2008 food consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). The acute dietary exposure analysis used tolerance-level residue estimates and assumed 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used 2003–2008 food consumption data from the USDA's NHANES/WWEIA. As to residue estimates in food, EPA conducted a partially refined chronic dietary (food and drinking water) exposure assessment for all established food uses of fenbuconazole. Average residues from field trials and 100 PCT were used. Empirical and default processing factors were used, as available.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that fenbuconazole should be classified as ''a possible human carcinogen'' and a linear approach has been used to quantify cancer risk. The cancer dietary exposure analysis used average field trial residue estimates and average PCT values. Empirical and default processing factors were used, as available.

iv. *Anticipated residue and PCT information.* Average residue values were used in the Agency's chronic and cancer assessment of fenbuconazole. Average percent crop treated estimates were used in the Agency's cancer assessment of fenbuconazole.

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

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.
- Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used the following average PCT estimates for fenbuconazole for assessing cancer risk: Almonds: 5%; apples: 5%; apricots: 5%; blueberries: 55%; cherries: 15%; grapefruit: 40%; nectarines: 5%; oranges: 5%; peaches: 15%; pecans: 10%; plums/prunes: 1%; sugar beets: 1%; tangelos: 10%; tangerines: 1%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain

that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which fenbuconazole may be applied in a particular area.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic and cancer dietary risk analyses and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for fenbuconazole in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fenbuconazole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm.*

Based on the (PRZM/EXAMS), the estimated drinking water concentrations (EDWCs) of fenbuconazole for acute exposures are estimated to be 24.1 parts per billion (ppb) for surface water and 0.031 ppb for ground water. For chronic exposures for non-cancer assessments are estimated to be 16.5 ppb for surface water and 0.031 ppb for ground water. For chronic exposures for cancer assessments are estimated to be 11.7 ppb for surface water and 0.031 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The PRZM/EXAMS 1-in-10-year annual peak surface water value of 24.1 ppb for peppers is greater than the SCI–GROW groundwater value of 0.031 ppb. As a result, the surface water value was used in the acute dietary analysis. The 1-in-10-year annual mean surface water value of 16.5 ppb for cherries is greater than the groundwater value of 0.031 ppb. As a result, the surface water value was used in the chronic dietary analysis. Finally, the 30-year annual mean surface water value of 11.7 ppb for cherries is greater than the groundwater value of 0.031 ppb. As a result, the surface water value was used in the cancer dietary analysis.

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

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(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.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fenbuconazole and any other substances. Although the conazole fungicides (triazoles) produce 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid), 1,2,4 triazole and its acid-conjugated metabolites do not contribute to the toxicity of the parent conazole fungicides (triazoles). The Agency has assessed the aggregate risks from the 1,2,4 triazole and its acid-conjugated metabolites (triazolylalanine and triazolylacetic acid) separately. The use of fenbuconazole on tea is not expected to quantitatively alter the dietary exposure estimates used in the most recent aggregate risk assessment for the common triazole metabolites because tea is not a significant consumption item and other conazoles are already registered for tea. The most recent triazole aggregate risk assessment (*Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address New Section 3 Registrations For Use of Difenoconazole and Mefentrifluconazole;* DP451447, dated May 15, 2019) can be found at *https://www.regulations.gov* at docket ID number EPA–HQ–OPP–2018–0002. Fenbuconazole does not appear to produce any other toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that fenbuconazole has a common mechanism of toxicity with other substances.

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* There is no indication of quantitative or qualitative susceptibility of rats or rabbits to *in utero* and/or postnatal exposure.

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

i. The toxicity database for fenbuconazole is complete.

ii. There is no indication that fenbuconazole is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that fenbuconazole results in increased susceptibility *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The exposure assessment was based on field-trial residues and modeled drinking water estimates that will not underestimate dietary exposure and risk. The acute dietary exposure analysis used tolerance-level residues and assumed 100 PCT. The chronic and cancer dietary exposure analyses used average field-trial residue estimates. The chronic (non-cancer) assessment assumed 100 PCT, and the cancer analysis made use of average PCT estimates. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fenbuconazole in drinking water. These assessments will not underestimate the exposure and risks posed by fenbuconazole.

E. Aggregate Risks and Determination of Safety

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

1. Acute risk. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fenbuconazole will occupy 3.0% of the aPAD at the 95th percentile of exposure for females 13–49 years old, the only population subgroup with a relevant endpoint.

2. Chronic risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fenbuconazole from food and water uses 6.8% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. The chronic risk estimate for the general U.S. population uses 2.5% of the cPAD. There are no residential uses for fenbuconazole.

3. Short-term risk. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). There are no registered residential uses for fenbuconazole, and therefore aggregate exposure and risk are equivalent to dietary exposure and risk, and these risk estimates are not of concern.

4. Intermediate-term risk. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). There are no registered residential uses for fenbuconazole, and therefore aggregate exposure and risk are equivalent to dietary exposure and risk, and these risk estimates are not of concern.

5. Aggregate cancer risk for U.S. population. Cancer risk was estimated at 1.8×10^{-6}. The Agency generally considers risks up to 3×10^{-6} to be within the negligible risk range and below the Agency's LOC. In addition, actual cancer risk is likely to be much lower, since the residue inputs were based on field trial data (as opposed to monitoring data) and used upper-bound PCT estimates.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Tolerance enforcement method 34–90–47R is available for determining residues of fenbuconazole, RH–9129, and RH–9130 in plant commodities through gas chromatography with a nitrogen phosphorous detector (GC–NPD). The method has undergone successful independent laboratory validation. The GC–NPD method TR 34–94–142 is adequate for collecting data on residues of fenbuconazole, RH–9129, and RH–9130 in livestock commodities.

These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established an MRL for fenbuconazole in tea.

C. Revisions to Petitioned-For Tolerances

The petitioner initially proposed a tolerance level of 10 ppm for residues in/on tea, dried and tea, instant, based on 1995 magnitude of the residue data reviewed by the Food Safety Commission of Japan. However, based on additional magnitude of the residue studies conducted in 2016 and 2017, the petitioner updated the proposed tolerance to 30 ppm in/on tea, dried and tea, instant. The proposed 30 ppm tolerance is in accordance with the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedure. Based on the residue data reviewed by the Food Safety Commission of Japan, the Agency concluded that the proposed tolerances of 30 ppm in/on tea, dried and tea, instant are appropriate.

V. Conclusion

Therefore, tolerances are established for residues of fenbuconazole and its lactone metabolites (*trans*- or *cis*-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)-2(3*H*)-furanone), in or on tea, dried and tea, instant at 30 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances 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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under 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(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 30, 2019.

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:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.480, add alphabetically entries for ''tea, dried'' and ''tea, instant'' to the table in paragraph (a) to read as follows:

§ 180.480 Fenbuconazole; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Tea, dried [2]	30
Tea, instant [2]	30
* * * * *	
* * * * *	

[2] There are no U.S. registrations for use of fenbuconazole on tea.

* * * * *

[FR Doc. 2019–23380 Filed 10–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0619; FRL–10000–06]

Pendimethalin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of pendimethalin in or on the leaf petiole vegetable subgroup 22B, monarda oil, monarda fresh leaves, rosemary oil, and rosemary fresh leaves. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 25, 2019. Objections and requests for hearings must be received on or before December 24, 2019, 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–2018–0619, 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: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 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 EPA's tolerance regulations at 40 CFR part 180 through

the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2018–0619 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before December 24, 2019. 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–2018–0619, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of December 21, 2018 (83 FR 65660) (FRL–9985–67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E8694) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the herbicide pendimethalin, including its metabolites and degradates, in or on the following raw agricultural commodities: Leaf petiole vegetables, subgroup 22B at 0.15 ppm; monarda, oil at 1.0 ppm; monarda, fresh leaves at 0.20 ppm; rosemary, oil at 1.0 ppm; and rosemary, fresh leaves at 0.20 ppm. That document referenced a summary of the petition prepared by BASF, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

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

III. Aggregate Risk Assessment and Determination of Safety

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

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

A. Toxicological Profile

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

The target organ for pendimethalin is the thyroid. Thyroid toxicity in chronic and subchronic rat and mouse studies was manifested as alterations in thyroid hormones (decreased total T4 and T3, increased percent of free T4 and T3), increased thyroid weight, and microscopic thyroid lesions (including increased thyroid follicular cell height, follicular cell hyperplasia, as well as follicular cell adenomas). Due to these effects, the Agency required that a developmental thyroid assay be conducted to evaluate the impact of pendimethalin on thyroid hormones, structure, and/or thyroid hormone homeostasis during development. A developmental thyroid study was submitted and demonstrated that there is no potential thyroid toxicity following pre- and/or post-natal exposure to pendimethalin.

There is no evidence that pendimethalin is a developmental, reproductive, neurotoxic, or immunotoxic chemical. There is no evidence of increased qualitative or quantitative susceptibility in the young. EPA classified pendimethalin as a ''Group C'' possible human carcinogen based on a statistically significant increased trend and pair-wise comparison between the high-dose group and controls for thyroid follicular cell adenomas in male and female rats. A non-quantitative approach (*i.e.,* non-linear, reference dose (RfD) approach) was used to assess cancer risk since mode-of-action studies are available to demonstrate that the thyroid tumors are due to a thyroid-pituitary imbalance, and also since pendimethalin was shown to be non-mutagenic in mammalian somatic cells and germ cells.

Specific information on the studies received and the nature of the adverse effects caused by pendimethalin as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document titled ''Pendimethalin—Human Health Risk Assessment to Support the Proposed New Uses on Leaf Petiole Vegetable Subgroup 22B, Monarda and

Rosemary'' on pages 37–41 in docket ID number EPA–HQ–OPP–2018–0619.

B. Toxicological Points of Departure/ Levels of Concern

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

A summary of the toxicological endpoints for pendimethalin used for human risk assessment is discussed in Unit III.B of the final rule published in the **Federal Register** of February 16, 2018 (83 FR 6975) (FRL–9973–03).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to pendimethalin, EPA considered exposure under the petitioned-for tolerances as well as all existing pendimethalin tolerances in 40 CFR 180.361. EPA assessed dietary exposures from pendimethalin in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for pendimethalin. In estimating acute dietary exposure, EPA used Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16. This software uses 2003–2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM–FCID, Version 3.16 software with 2003–2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA used tolerance-level residues and 100 PCT for all commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to pendimethalin. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii., chronic exposure.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for pendimethalin. Tolerance level residues and 100 PCT were assumed for all food commodities.

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

Based on the Pesticide Root Zone Model Ground Water (PRZM GW) and Surface Water Concentration Calculator (SWCC) models, the estimated drinking water concentrations (EDWCs) of pendimethalin for acute exposures are estimated to be 96.4 parts per billion (ppb) for surface water and 4.38×10^{9} ppb for ground water. For chronic exposures they are estimated to be 9.73 ppb for surface water. For chronic exposures, pendimethalin did not reach groundwater even after running the model with an extended 100-year weather file.

For the acute dietary risk assessment, the water concentration value of 96.4 ppb was used to assess the contribution to drinking water. For the chronic dietary risk assessment, the water concentration of value 9.73 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Pendimethalin is currently registered for the following uses that could result in residential exposures: Turf, home gardens, and ornamentals. EPA assessed residential exposure using the following assumptions. First, for handlers, it is assumed that residential use will result in short-term (1 to 30 days) duration dermal and inhalation exposures. Second, residential post-application exposure is also assumed to be short-term (1 to 30 days) in duration, resulting from the following exposure scenarios: (1) Gardening: Adults (dermal) and children 6 < 11 years old (dermal); (2) physical activities on turf: Adults (dermal) and children 1–2 years old (dermal and incidental oral); (3) mowing turf: Adults (dermal) and children 11 < 16 years old (dermal); and (4) exposure to golf courses during golfing: Adults (dermal), children 11 < 16 years old (dermal), and children 6 < 11 years old (dermal).

EPA did not combine exposure resulting from adult handler and post-application exposure resulting from treated gardens, lawns, and/or golfing because the conservative assumptions and inputs within each estimated exposure scenario would result in an overestimate of adult exposure. EPA selected the most conservative adult residential scenario (adult dermal post-application exposure from gardening) as the contributing source of residential exposure to be combined with the dietary exposure for the aggregate assessment. The children's oral exposure is based on post-application hand-to-mouth exposures. To include exposure from object-to-mouth and soil ingestion in addition to hand-to-mouth would overestimate the potential for oral exposure. However, there is the potential for co-occurrence of dermal and oral exposure, since the toxicological effects from the dermal and oral routes of exposure are the same. As a result, the children's aggregate assessment combines post-application dermal and oral exposure along with dietary exposure from food and water. Further information regarding EPA standard assumptions and generic inputs for residential

exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

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

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

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* There was no indication of pre- or post-natal qualitative or quantitative increased susceptibility in the developmental studies in rats and rabbits or the 2-generation reproduction studies in rats. A developmental thyroid toxicity study demonstrated that there is no potential thyroid toxicity following pre- and/or post-natal exposure to pendimethalin.

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

i. The toxicity database for pendimethalin is complete. Although a subchronic inhalation study was not available in the database, EPA determined that one is not needed at this time based on a weight-of-evidence analysis, considering the following: (1) All relevant hazard and exposure information, which indicates its low acute inhalation toxicity; (2) its physical/chemical properties, which indicate its low volatility; and (3) the use of an oral POD that results in a residential inhalation margin of exposure (MOE) more than 10X the level of concern (in the case of pendimethalin MOE = 30 based on thyroid POD).

ii. There is no indication that pendimethalin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that pendimethalin results in increased susceptibility *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study. In addition, a developmental thyroid toxicity study demonstrated that there is no potential thyroid toxicity following pre- or post-natal exposure to pendimethalin.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to pendimethalin in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by pendimethalin.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to pendimethalin will occupy 2.1% of the aPAD for all infants less than 1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to pendimethalin from food and water will utilize 2.4% of the cPAD for children one to two years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of pendimethalin is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Pendimethalin is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to pendimethalin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 130 for adults and 92 for children 1 to 2 years old, the two population subgroups receiving the greatest combined dietary and non-dietary exposure. Because EPA's level of concern for pendimethalin is a MOE of 30 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, pendimethalin is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for

evaluating intermediate-term risk for pendimethalin.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit III.A., EPA has determined that an RfD approach based on the chronic point of departure is appropriate for evaluating cancer risk. As there are not chronic aggregate risks of concern, there are no cancer aggregate risk concerns.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology, gas chromatography with electron capture detection (GC/ECD), is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

The Codex has not established any MRLs for pendimethalin for the crops covered by this action.

C. Revisions to Petitioned-For Tolerances

The Agency is establishing tolerances for monarda, fresh leaves; rosemary, fresh leaves; monarda, oil; and rosemary, oil to be consistent with the Organization for Economic Co-operation and Development (OECD) rounding class practice (at 0.2 ppm and 1 ppm instead of at 0.20 ppm and 1.0 ppm). For the joint review of the pendimethalin on celery data, the U.S. EPA and Canada PMRA have used the OECD calculation procedures to determine the recommended maximum residue level (MRL). Although the Agency-calculated level using the OECD procedure is the same as the petitioned-for level of 0.15 ppm, PMRA is proposing to recommend a MRL of 0.2 ppm for pendimethalin in celery. The different levels are a result of different proposed use rates in the U.S. and Canada. EPA is therefore establishing a U.S. tolerance of 0.2 ppm for the leaf petiole vegetable subgroup 22B for harmonization purposes with Canada.

V. Conclusion

Therefore, tolerances are established for residues of pendimethalin, including its metabolites and degradates, in or on the leaf petiole vegetable subgroup 22B at 0.2 ppm; monarda, fresh leaves at 0.2 ppm; monarda, oil at 1 ppm; rosemary, fresh leaves at 0.2 ppm; and rosemary, oil at 1 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances 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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 18, 2019.

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:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.361, add alphabetically the entries ''Leaf petiole vegetable subgroup 22B''; ''Monarda, fresh leaves''; ''Monarda, oil''; ''Rosemary, fresh leaves''; and ''Rosemary, oil'' to the table in paragraph (a)(1) to read as follows:

§ 180.361 Pendimethalin; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million
* * * * *	
Leaf petiole vegetable subgroup 22B	0.2
* * * * *	
Monarda, fresh leaves	0.2
Monarda, oil	1
* * * * *	
Rosemary, fresh leaves	0.2
Rosemary, oil	1
* * * * *	

* * * * *

[FR Doc. 2019–23382 Filed 10–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2018–0599; FRL–9998–88]

Sulfoxaflor; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of sulfoxaflor in or on rice grain, rice hulls, and avocados. Dow AgroSciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 25, 2019. Objections and requests for hearings must be received on or before December 24, 2019, 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–2018–0599, 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: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 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 EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2018–0599 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before December 24, 2019. 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–2018–0599, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 7, 2019 (84 FR 26630) (FRL–9993–93), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8338) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of sulfoxaflor (1-(6-trifluoromethylpyridin-3-yl)ethyl)(methyl)-oxido-l4-sulfanylidenecyyanamide), in or on the following raw agricultural commodities: Rice, grain at 5 parts per million (ppm); rice, straw at 5 ppm; rice, hulls at 14 ppm; and avocado, whole fruit at 0.15 ppm.

One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit IV.C.

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from what the petitioner requested, as authorized under FFDCA section 408(d)(4)(A)(i). EPA's explanation for those variations are contained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for sulfoxaflor in or on rice and avocado.

On July 24, 2019, EPA published a final rule establishing a tolerance for residues of sulfoxaflor in or on multiple commodities based on the Agency's conclusion that those tolerances are safe for the general population, including infants and children (84 FR 35546) (FRL–9995–63). EPA's exposure assessment supporting the July 24, 2019 final rule included exposure from use of sulfoxaflor on both avocado and rice commodities, but these tolerances were not established at the time because a Notice of Filing for the petition for these commodities was still pending and the statutory public comment period was still open. Because the toxicity profile of sulfoxaflor has not changed since that rule was published, and because residues of sulfoxaflor on both avocado and rice were included in the dietary exposure and risk assessment supporting that rule, EPA is incorporating the findings in the preamble to that July 24, 2019 final rule into this rulemaking.

Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the July 24, 2019 **Federal Register** action, as well as the new sulfoxaflor tolerances on rice and avocado can be found at *http://www.regulations.gov* in the documents entitled: ''*Sulfoxaflor. Human Health Risk Assessment for New Food Uses on Numerous Crops, Ornamentals Growing in Greenhouses and Nurseries and Tree Farms and Plantations*'' and ''*Sulfoxaflor. Human Health Risk Assessment for New Food Uses on Artichoke, Asparagus, Bushberry, Caneberry and Sunflower, and Multiple Crop Group Conversions.*'' The documents may be found in docket ID numbers EPA–HQ–OPP–2018–0599 and EPA–HQ–OPP–2018–0179.

Therefore, based on the risk assessments and information described above, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to sulfoxaflor residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

High performance liquid chromatographic methods with positive-ion electro spray interface (ESI) and tandem mass spectrometric detection (LC/MS/MS) were previously reviewed and found to be acceptable for tolerance enforcement of sulfoxaflor residues (the two metabolites, X11719474 and X11721061, are also quantitated). The limit of quantitation (LOQ), determined as the lowest level of method validation (LLMV), is 0.010 ppm in all matrices.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

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

C. Response to Comments

One comment was received that stated in part that tolerance levels should be zero because people do not need to be exposed to more poison. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that these sulfoxaflor tolerances are safe. The commenter has provided no information supporting a contrary conclusion.

D. Revisions to Petitioned-For Tolerance

Although proposed by the petitioner, a tolerance is not being established on rice straw because the Agency no longer considers this commodity a significant livestock feed item, per the Chemistry Science Advisory Council (ChemSAC) memorandum on livestock feed (Revisions of Feedstuffs in Table 1 of OPPTS Test Guideline 860.1000 and Guidance on Constructing Maximum Reasonably Balanced Diets (MRBD); ChemSAC; 30 June 2008). Also, based on results of the rice processing study, the Agency is establishing a tolerance of 15 ppm on rice hulls, rather than at 14 ppm as requested. This is in accordance with the pertinent rounding class of the Organization for Economic Development and Cooperation (OECD) tolerance calculation procedure.

V. Conclusion

Therefore, tolerances are established for residues of sulfoxaflor in or on avocado at 0.15 ppm; rice, grain at 5 ppm; and rice, hulls at 15 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances 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), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: September 30, 2019.

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:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.668,

■ i. Add alphabetically entries for ''Avocado''; ''Rice, grain''; and ''Rice, hulls'' to the table in paragraph (a) to read as follows:

§ 180.668 Sulfoxaflor; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Avocado	0.15
* * * * *	
Rice, grain	5
Rice, hulls	15
* * * * *	

* * * * *

[FR Doc. 2019–23384 Filed 10–24–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 27

[WT Docket No. 18–120; FCC 19–62]

Transforming the 2.5 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission or FCC) takes another step towards making more mid-band spectrum available for next generation wireless services benefitting all Americans. Specifically, the Commission transforms the regulatory framework governing the 2.5 GHz band (2496–2690 MHz), which is the single largest band of contiguous spectrum below 3 gigahertz.

DATES: Effective April 27, 2020, except for amendments to §§ 27.14(u) and (v) and 27.1204, which are effective November 25, 2019.

FOR FURTHER INFORMATION CONTACT: John Schauble of the Wireless Telecommunications Bureau, Broadband Division, at (202) 418–0797 or *John.Schauble@fcc.gov.* For information regarding the PRA information collection requirements contained in this PRA, contact Cathy Williams, Office of Managing Director, at (202) 418–2918 or *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, WT Docket No. 18–120, FCC 19–62, adopted on July 10, 2019 and released on July 11, 2019. The complete text of this document is available for public inspection and copying from 8 a.m. to 4:30 p.m. Eastern Time (ET) Monday through Thursday or from 8 a.m. to 11:30 a.m. ET on Fridays in the FCC Reference Information Center, 445 12th Street SW, Room CY–A257, Washington, DC 20554. The complete text is available on the Commission's website at *https://docs.fcc.gov/public/attachments/FCC-19-62A1.pdf,* or by using the search function on the ECFS web page at *http://www.fcc.gov/cgb/ecfs/.* Alternative formats are available to persons with disabilities by sending an email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty).

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) requires that an agency prepare a regulatory flexibility analysis for notice

and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) concerning the possible impact of the rule changes contained in this *Report and Order* on small entities. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Notice of Proposed Rulemaking (NPRM)* released in May 2018 in this proceeding (83 FR 26396, June 7, 2018). The Commission sought written public comment on the proposals in the *NPRM,* including comments on the IRFA. No comments were filed addressing the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

Paperwork Reduction Act

The requirements in §§ 27.14(u) and 27.1204 constitute new or modified collections subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. They will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new or modified information collection requirements contained in this proceeding. In addition, the Commission notes that, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the Commission previously sought, but did not receive, specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees. The Commission describes impacts that might affect small businesses, which includes more businesses with fewer than 25 employees, in the Final Regulatory Flexibility Analysis.

Congressional Review Act

The Commission will send a copy of this Report & Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act. *See* 5 U.S.C. 801(a)(1)(A). In addition, the Commission will send a copy of the *Report and Order,* including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the *Report and Order,* and FRFA (or summaries thereof) will also be published in the **Federal Register**.

I. Introduction

1. In this *Report and Order,* the Commission takes another step towards implementing its comprehensive strategy to make additional high-band, mid-band, and low-band spectrum available for next generation wireless services. Specifically, the Commission transforms the regulatory framework governing the 2.5 GHz band (2496–2690 MHz), which is the single largest band of contiguous spectrum below 3 gigahertz. Too much of this spectrum, which is prime spectrum for next generation mobile operations, including 5G, has lain fallow for more than twenty years. In order to move this spectrum into the hands of those who will provide service, including 5G, to Americans across the country, and particularly in rural and Tribal areas, the Commission is replacing an outdated regulatory regime, developed in the days when educational TV was the only use envisioned for this spectrum, with one that not only gives incumbent users more flexibility in how they use the spectrum, but also provides opportunities for additional entities to obtain access to unused 2.5 GHz spectrum. Importantly, the reforms the Commission adopts in this *Report and Order* will make valuable mid-band spectrum available for the mobile services on which consumers increasingly rely and which is critical to maintaining American leadership in the next generation of wireless connectivity.

II. Background

2. The 2.5 GHz band, which extends from 2496 to 2690 MHz, is comprised of 20 channels designated for Educational Broadband Service (EBS), 13 channels designated for commercial Broadband Radio Service (BRS), and a number of small guard band channels. EBS licensees are authorized to operate on the A, B, C, D, and G channel groups, with each group comprised of three 5.5 megahertz-wide channels in the lower or upper band segment and one 6 megahertz-wide channel in the middle band segment. Currently, there are 1,300 EBS licensees holding 2,193 licenses.

3. Only specified entities are eligible to hold an EBS license, specifically (1) accredited public and private educational institutions, (2) governmental organizations engaged in the formal education of enrolled students, and (3) nonprofit organizations whose purpose is educational and include providing educational and instructional television materials to accredited institutions and governmental organizations.

4. The Commission rules permit EBS licensees to lease their excess capacity to non-educational entities to use for non-educational purposes. And most EBS licensees do so. There are 2,087 active leases of EBS spectrum, compared with 2,193 licenses.

5. There are special requirements applicable to EBS excess capacity leases that do not apply in other services. Because the Commission's rules require EBS licensees to use their spectrum to further their educational missions, any excess capacity lease entered into by an EBS licensee must reserve a minimum of 5% of its spectrum capacity for the licensee/lessor and the licensee must use that capacity to provide 20 hours of educational usage per channel per week. Under existing rules, the Commission generally prohibits EBS licensees from leasing their facilities for a term longer than 30 years. Also, lessees are required to provide EBS lessors with the opportunity to revisit their lease terms at years 15, 20, and 25 to review their ''educational use requirements in light of changes in educational needs, technology, and other relevant factors and to obtain access to such additional services, capacity, support, and/or equipment as the parties shall agree upon in the spectrum leasing arrangement to advance the EBS licensee's educational mission.'' Those rules do not apply to leases that were entered into before January 10, 2005; such leases were grandfathered under the previous ITFS rules, which allowed a term of no more than fifteen years.

6. EBS presents two special challenges which are largely not present in other bands: a long-standing failure to make spectrum available, particularly in rural areas, and an unusual licensing scheme. Incumbent EBS licenses cover only about one half of the geographic area of the United States in any given channel. The 2.5 GHz spectrum remains largely unassigned in much of the rest of the country, especially in rural areas west of the Mississippi River.

7. The Commission suspended the processing of applications for new EBS licenses (and for major changes to existing EBS licenses) in 1993. Since then, the Commission has only opened two filing windows for EBS applications—in 1995, for new construction permits and major changes to existing EBS facilities, and in 1996, to allow for the filing of EBS modification applications and amendments to pending EBS applications proposing to co-locate with an authorized wireless cable facility. Thus, the last regular opportunity to apply for a new EBS license was in 1995.

8. In general, each EBS license is based on a circular Geographic Service Area (GSA) with a 35-mile radius (with an area of approximately 3,850 square miles). Due to a historical license modification process the Commission adopted in 2005, however, many EBS licenses have much smaller, irregular GSAs. Specifically, many EBS licenses had their 35-mile radius circles reduced when the Commission converted their Protected Service Areas (PSAs) to GSAs through the ''splitting-the-football'' process.[1]

9. On May 10, 2018, the Commission released the *Notice of Proposed Rulemaking* (*NPRM*), 83 FR 26396, in this proceeding that explored ways to make this unused spectrum available for more flexible use to facilitate the deployment of next generation wireless services, including 5G, to all Americans. The *NPRM* proposed to rationalize the geographic service areas of EBS licenses and to provide additional flexibility to current EBS licensees in the use of the spectrum. It also sought comment on opening up priority windows for access to the spectrum by certain groups, such as Tribal Nations; and it proposed to assign the remaining white space through geographic area licenses for commercial use subject to competitive bidding; and sought comment on regulatory requirements for new EBS licensees.

10. The Commission received 304 comments (including express comments) and 29 reply comments on the *NPRM.*

III. Discussion

11. To further the Commission's goal of ensuring that this fallow spectrum is used to provide high-speed broadband service, particularly in rural areas, the Commission moves quickly to assign the remaining spectrum in this band to those who will use it to provide service.[2] Specifically, the Commission will hold a Tribal priority window to enable Tribal nations an opportunity to obtain 2.5 GHz licenses to provide service on rural Tribal lands. This window will be followed immediately by a system of competitive bidding for the remaining white spaces. In conjunction with the Commission's effort to quickly license the remaining spectrum in this band to entities that will use it, the Commission also will replace the outdated regulatory regime for EBS with one of flexible use, thus making this valuable mid-band spectrum more available for advanced wireless services, including 5G.

A. Rationalizing Incumbent 2.5 GHz Band Holdings

12. The Commission takes a series of steps to provide existing EBS licensees with additional flexibility. First, in order to provide EBS licensees with additional flexibility and to facilitate the most efficient use of the EBS spectrum through a market-based mechanism, the Commission adopts the *NPRM's* proposal to eliminate the EBS eligibility requirements, including for licenses granted via waiver of the filing freeze. Second, as part of the Commission's efforts to remove unnecessary regulatory barriers and align the EBS licenses with the flexible use policies used in similar spectrum bands, the Commission adopts its proposal in the *NPRM* to eliminate the educational use requirements for EBS licenses. Third, the Commission adopts the *NPRM's* proposal to eliminate restrictions on EBS leases entered into under its Secondary Markets policies on a going forward basis. The Commission clarifies that nothing in its decisions is intended to affect or change the terms of any private contractual arrangement or any provisions in existing leases. Finally, the Commission declines to adopt the *NPRM's* proposal to rationalize incumbent licenses to align with pre-existing geographic areas.

1. Eliminating Eligibility Restrictions

13. As noted by commenters that support elimination of the eligibility restrictions, eliminating eligibility restrictions will promote more efficient use of the spectrum, improve the industry's ability to attract capital, and make this spectrum more appealing for commercial operators to include in their long-term service plans. Therefore, once the rules become effective, both incumbent EBS licenses and new EBS licenses once issued will be free of the eligibility restrictions, and EBS licensees may assign or transfer their licenses freely. In taking this step, the Commission better aligns these licenses with the flexible use licensing policies used in similar spectrum bands, which generally feature open eligibility. Moreover, taking this step is also consistent with the Commission's historical progression of granting increasing flexibility to EBS licensees, which has been an effective means of promoting more efficient use of the 2.5 GHz band.

14. The circumstances that led to the creation of a dedicated educational service no longer exist. Substantial technological changes over the last 30 years enable any educator with a broadband connection to access a myriad of educational resources—a content distribution model that does not require dedicated educational spectrum licensed to educational institutions. Only a handful of EBS licensees have deployed their own networks or use their EBS licenses in a way that requires dedicated spectrum. Instead, most licensees rely on lessees to deploy and operate broadband networks and use the leases as a source for revenues or devices. Moreover, as noted below, there are a multiplicity of other sources of educational programming available to institutions with broadband connections. All of these factors support eliminating the eligibility restrictions at this time.

15. The Commission does not believe that eliminating EBS eligibility restrictions will result in negative consequences for the educational community. Despite some claims to the contrary, eliminating eligibility requirements will not disrupt existing arrangements. Granting incumbent licensees additional flexibility to transfer or assign their licenses will not affect existing leases because: (1) The decision about whether to lease or transfer or assign a license remains with the EBS licensee, and (2) the Commission's actions in this *Report and Order* do not affect the validity of existing leases and other contractual arrangements. The services currently provided by EBS licensees will continue uninterrupted, including those provided by Mobile Beacon and Mobile Citizen pursuant to their leases with Sprint, unless the parties themselves decide otherwise. The Commission is not persuaded that eliminating the eligibility restrictions will jeopardize the public-private partnerships

[1] ''Splitting-the-football'' refers to a process initially used informally by licensees in the MDS and ITFS industry to handle interference issues in GSAs that overlap. (''The area for incumbent site-based licensees that is bounded by a circle having a 35 mile radius and centered at the station's reference coordinates, which was the previous PSA entitled to incumbent licensees prior to January 10, 2005, and is bounded by the chord(s) drawn between intersection points of the licensee's previous 35-mile PSA and those of respective adjacent market, co-channel licensees.'').

[2] On May 13, 2019, SHLB, NACEPF, Mobile Beacon, Voqal, National Digital Inclusion Alliance and Public Knowledge filed a request that the Commission seek further comment and delay a decision in this proceeding. *See* SHLB, NACEPF, Mobile Beacon, Voqal, National Digital Inclusion Alliance and Public Knowledge May 13 *Ex Parte, see also* Dept. of Ed. June 7 *Ex Parte* at 8. Further delay in this proceeding is not warranted. All parties have had ample opportunity to provide information through comments, reply comments, and *ex parte* presentations. Indeed, SHLB and its partners were free to provide economic analysis and information on educational use at the comment or reply comment stage. The actions the Commission takes was clearly identified in the *NPRM.* Given the critical need to make additional mid-band spectrum available, it is entirely appropriate to act now.

promoted by the Commission's leasing rules that have facilitated the construction of networks, which have benefitted both the educational institutions and their network partners. Providing additional flexibility to incumbent EBS licensees by eliminating the eligibility restrictions will help ensure that the licensee retains control of decisions about how the license is to be used, including decisions about whether, under what terms, and to whom to transfer or assign the license. Incumbent EBS licensees that wish to retain their licenses [3] and continue participating in public-private partnerships may do so; incumbent EBS licensees that wish to transfer or assign their licenses will now have greater ability to do so.

16. The Commission therefore rejects as speculative and unpersuasive the assertions of some commenters that eliminating eligibility restrictions will lead to existing EBS licensees' losing negotiating leverage and will give commercial entities the incentive and ability to offer licensees unfavorable sale terms rather than new or renewed leases. For the same reasons, the Commission rejects allegations that permitting transfer or assignment of incumbent EBS licensees will hurt education generally, even if it benefits individual licensees. Providing licensees with additional flexibility to transfer or assign their licenses gives them greater power to put the licenses to use in the manner that suits their educational objectives. The Commission expects that incumbent licensees will make decisions about assigning or transferring their licenses based on the best interests of their educational institution.

17. Contrary to the concerns of some commenters, the Commission does not believe that continuing to apply EBS eligibility restrictions is necessary to ensure that commercial entities meet the needs of underserved communities. Appropriate performance requirements, such as those adopted herein, can ensure that licensees actually use their spectrum to offer service. Moreover, nothing in this proceeding affects the ability of commercial entities to provide broadband to entities eligible for E-Rate funding, which is another way to ensure that schools and libraries in underserved communities are provided with broadband access. In addition, those incumbent EBS licensees that retain their licenses can continue to meet the educational and other needs of their communities. Finally, the priority window and competitive bidding mechanisms adopted herein will provide additional opportunities for the deployment of broadband service to rural unserved market areas using 2.5 GHz spectrum.

18. The Commission rejects claims that the Commission's prior decisions to establish ITFS in 1963 and to maintain the eligibility restrictions in 2004 support continuation of the EBS eligibility restriction. When the 2.5 GHz band originally was designated for educational use in 1963, there was a demonstrated need for dedicated spectrum for educational television services. When, in 2004—three years before the introduction of the smartphone—the Commission decided against revising the eligibility restrictions, the 2.5 GHz band was just beginning a major transition, as it moved from an analog television service to a broadband service accompanied by substantial technical changes. In that context, the Commission concluded that it was premature to eliminate the restrictions at that time. In contrast, this band now is used primarily for broadband, and it resembles flexible use bands such as the PCS or AWS bands more than it resembles the ITFS band of old. Indeed, even the current educational use requirements—to retain 5% of capacity for educational use and to use each channel at least 20 hours per week for educational purposes—have little relevance to the way this band is being used. In the exercise of the Commission's spectrum management responsibilities, the Commission believes that it is more appropriate in these circumstances to address the critical shortage of flexible use mid-band spectrum necessary to promote the deployment of wireless broadband devoted to the wide range of 5G uses.

19. Further, the Commission is not persuaded by the economic study submitted on behalf of SHLB in support of maintaining the eligibility requirements, which it finds to be premised on an unrealistic deployment model. The SHLB Economic Study discusses the services offered by Mobile Citizen and Mobile Beacon pursuant to their agreement with Sprint, as well as those offered by self-deployed EBS networks, and it constructs a framework to measure the economic benefit of retaining eligibility restrictions assuming that educational licensees offer broadband service at $15/month. However, as noted previously, most educational licensees have chosen not to deploy their own networks. Indeed, none of the self-deployed educational networks identified by SHLB offer service on a regular basis to the general public at $15/month.[4] While economic and social benefits would flow from increased broadband adoption, SHLB has not shown that educators could sustain a broadband system at the $15/month price point they studied. Finally, the study in the Commission's view does not adequately address the problem of the digital divide. Specifically, while Mobile Citizen and Mobile Beacon offer access at $10/month pursuant to their agreement with Sprint, their associated companies hold EBS spectrum licenses in major and more densely populated markets. The Commission cannot infer from this that new EBS licenses in rural areas would be able to negotiate similar agreements with Sprint or another provider, particularly given the higher cost of deploying mid-band spectrum in rural areas.

20. Further, the SHLB Economic Study claims that the economic and social benefits from assigning the 2.5 GHz spectrum via an overlay auction are less than if the licenses were assigned to educational institutions and/or Tribal nations. The Commission disagrees. The Commission finds that auctioning overlay licenses for remaining white spaces will be a more efficient and effective means of addressing the digital

[3] The Commission cautions incumbent EBS licensees concerning the eligibility and other requirements of its existing EBS rules, including the licensee's educational purposes, the provision of educational and instructional television material to accredited institutions and government organizations, the reception and use by receive sites of the licensee's educational usage, the specific additional obligations of nonlocal applicants, and the minimum 5% reservation of channel capacity. 47 CFR 27.1201(a), 27.1214. Based on recent allegations that several national, non-profit licensees have not complied with the Commission's eligibility and other rules, *see, e.g.,* Letter from Commissioner Brendan Carr to George Bott, President, Rockne Educational TV (July 3, 2019), the Commission directs the Wireless Telecommunications Bureau and the Enforcement Bureau to investigate such allegations and take appropriate action based on their findings.

[4] SHLB identifies seven ''infrastructure-based'' EBS networks. SHLB Economic Study at 22 (Table 2–3). Two of the networks (Havasupai Tribal Council and Nisqually Indian Tribe) are tribal networks that are not relevant here. NMU charges $34.95/month to the general public, $24.95/month for alumni and veterans, and $19.95/month for students. *See https://www.nmu.edu/ean/.* Kings County charges $30/month for fixed access and $40/month for mobile access, with 50% discounts for students. *See https://www.kingscoe.org/domain/45* (Internet Fees, Prepaid Service). Imperial County, California's network is still in the pilot phase and is seeking donations to support its operations. *See https://www.icoe.org/about-icoe/borderlink.* It is unclear that the Louisa County, Virginia network is in fact operating. In its most recent filing concerning its special temporary authority, Louisa County reported that it was working to construct its system. *See* File No. 0008360114, Extension Request (filed Sep. 7, 2018). Finally, based on press reports, Albemarle County's system is only available to students. *See* Alison DeNisco, *High speed internet and free internet meet* (July 25, 2017), *https://districtadministration.com/high-speed-internet-and-free-internet-meet/.*

divide, as new EBS licensees will have both the market incentives and flexibility to pursue the most efficient deployment of this spectrum. The Commission notes that the Commission for over a quarter-century has successfully assigned spectrum via auction. It has recognized that spectrum auctions allow market forces to determine the highest and best use of scarce spectrum and the highest value user. The SHLB Economic Study not only fails to recognize the efficiency of spectrum auctions, but it also understates the potential benefits of an overlay auction because its commercial deployment model only considers deployment to entire counties, and it precludes deployment to parts of counties, which would greatly expand the potential scope of commercial deployment after an auction. The SHLB Economic Study also fails to consider complementarities that EBS spectrum may have with other spectrum bands. As noted above, the Commission has a comprehensive strategy to make additional high-band, mid-band, and low-band spectrum available, and wireless providers can combine these different bands to better achieve the best 5G coverage and capacity possible. Finally, the SHLB Economic Study is mistaken in concluding that there is no ''economic surplus'' from an overlay auction because it ''would not allow commercial carriers to launch more affordable offerings.'' Additional spectrum may lower network costs for service providers (*e.g.,* by eliminating the need for cell-splitting), thus leading to more affordable plans for American consumers.

21. In addition, to the extent that SHLB suggests that the Commission impose some sort of rate regulation on new EBS licensees, it fails to consider the disincentive that such a requirement would create to using these licenses to provide broadband service, especially in conjunction with similar bands used for broadband. That disincentive would be particularly significant given the fact that today's networks use a mixture of spectrum bands, and the 2.5 GHz band represents key mid-band spectrum for the deployment of 5G. Indeed, while CTN and NEBSA support the existing eligibility requirements, they do not see the proposal around which the SHLB Economic Study is based as workable. To be clear, nothing the Commission adopts prevents existing EBS licensees from pursuing opportunities with commercial service providers to provide broadband to the public; in fact, the Commission's action allows current EBS licensees flexible use of the full amount of spectrum they hold. Finally, the desire of entities such as Mobile Citizen and Mobile Beacon to expand their broadband service offerings to the general public using 2.5 GHz spectrum underscores the importance of making this spectrum available as quickly as possible.

22. There is no reason why those who hold licenses granted pursuant to waiver of the filing freeze should not have the same rights to transfer or assign or lease their licenses as other incumbent EBS licensees, and thus the Commission will permit those who hold licenses granted pursuant to waiver to freely assign or transfer their licenses. The existence of the filing freeze justified treating these licenses differently at the time they were granted, including subjecting the licenses to significant conditions such as prompt build-out and a prohibition on leasing. Now that these licensees have been operating and providing service in compliance with these conditions, and the filing freeze is being lifted with the upcoming Tribal priority window and competitive bidding opportunity, the Commission sees no reason to continue to apply different rules to them.[5]

23. To effectuate the Commission's decision to eliminate the EBS eligibility restriction, the Commission will eliminate existing § 27.1201 of the Commission's rules. In addition, the Commission will amend its secondary market leasing rules to eliminate the EBS-specific exception to the rule that a lessee must be eligible to hold a license in the service in which it is leasing spectrum. Since EBS will now be a service with open eligibility, the exception will no longer be necessary.

2. Educational Use Requirements

24. The Commission finds it is in the public interest to give licensees flexibility to put 2.5 GHz spectrum to its most efficient use, rather than maintaining or updating outmoded educational use requirements that have not been changed since 1998. Licensees holding licenses in the 2.5 GHz band, whether obtained before or after the adoption of this *Report and Order,* will not be required to use these licenses to fulfill an educational mission, although they are still permitted to do so.

25. This decision is consistent with the Commission's other decisions in this item to increase flexibility and eliminate outdated EBS requirements. The primary purpose of the educational use requirements was to ensure that educational licensees were using the spectrum for educational purposes, in order to ''safeguard[ ] the primary educational purpose of the ITFS spectrum allocation.'' If the Commission allows non-educators to hold licenses directly, it makes little sense to retain these restrictions on spectrum use. Furthermore, the Commission believes that eliminating these requirements is the best means of promoting flexibility, which ultimately will promote the deployment of broadband and allow markets to direct spectrum to its most productive use, for the benefit of educational institutions and all Americans.

26. As the Commission stated in the *NPRM,* the educational use requirements have not been updated since 1998 and were based on the use of analog video. Circumstances have changed radically since the Commission established ITFS. In 1963, there were very limited means of distributing educational programming to students, and a dedicated means of distributing such programming made sense. Now, as WCAI notes, ''broadband gives all educators—not just those lucky enough to be EBS licensees—the ability to provide access to educational materials to whomever they choose.'' The internet is a far more prevalent and efficient mechanism for distributing content. T-Mobile compares the efficiency of internet video streaming (for live events) or the downloading of compressed video files (for recorded material) over generic broadband digital connections versus using dedicated video transmissions. Furthermore, educators also use broadband to communicate with peers, collaborate across platforms, and research. Moreover, most current EBS licensees have abandoned use of EBS as a closed, dedicated means of distributing educational content. The educational use of the 2.5 GHz band has become indistinguishable from the commercial broadband service offered by the commercial lessee, with most EBS licensees or their commercial lessees providing digital broadband service, offered 24/7, at the school itself,

[5] Some commenters assert that the EBS application filing freeze, and not EBS eligibility restrictions, is the main cause of the inefficient use of EBS spectrum. CoSN Comments at 2–4; EBPARC Comments at 9–10; NEBSA/CTN Comments at 3–8. Without question, the EBS filing freeze contributed to underuse of the EBS band in some locations. By the Commission's actions in this item, including eliminating eligibility restrictions and education use requirements, establishing a priority filing window for new licenses for rural Tribal lands, and determining to assign the remaining unassigned frequencies through competitive bidding, the Commission provides a path forward to remedy this longstanding situation. However, the fact remains that with limited exception, most EBS licensees lease their spectrum to commercial operators, and meet their educational requirements providing services that do not require dedicated EBS spectrum.

at home, or anywhere within the licensee's GSA. Even if there were a rationale for maintaining the educational use requirements in the absence of eligibility restrictions, the Commission sees no workable set of requirements in this record. Commenters recommend that the Commission adopt a large and diverse set of potential requirements, ranging from new metrics differentiated by institution size to certification requirements to price mandates.

27. But the alternative educational use requirements proposed by commenters would neither facilitate broadband deployment nor be workable for licensees or commercial operators. Requiring a commercial operator to designate a fixed percentage of capacity for educational use is not an appropriate requirement when it is not clear how much capacity future networks will have or how much capacity most educational institutions will need or be able to use. Similarly, imposing rate regulation on new EBS licensees offering broadband service to consumers likely would create a disincentive to providing broadband service and would establish a regulatory requirement that would make it more difficult to use the band in conjunction with similar bands used for broadband. There is a large difference between the voluntary partnership entities such as Mobile Citizen and Mobile Beacon have negotiated to facilitate discounted broadband access and a regulatory mandate that would be a form of price control. The Commission also agrees with NEBSA/CTN that it is difficult to see how such a requirement would be defined and enforced.

28. The Commission is sensitive to the concerns raised by Sprint and NEBSA/CTN that any changes it makes not disrupt any existing leases. The Commission clarifies that nothing in its decision to remove the educational use requirement is intended to affect or change the terms of any private contractual arrangement or any provisions in existing leases that may provide a licensee with airtime, equipment, or capacity. In other words, if a lease negotiated under the old rules provides that a licensee shall receive services or equipment from a lessee, the Commission's decision does not change or nullify the provisions of that lease.

29. Finally, the Commission disagrees with NACEPF that the educational use requirements are one of the few tools the Commission has that can address the homework gap. There are many other spectrum bands that educators may use if they do not have access to 2.5 GHz spectrum, such as 5 GHz Wi-Fi or General Authorized Access in the 3.5 GHz CBRS band, and as mentioned above, commercial services developed using licensed spectrum are broadly deployed (certainly more so than services relying on current EBS spectrum). In addition, the Commission has for years focused on providing connectivity to millions of students and library patrons through its E-Rate program.

3. Eliminating Leasing Restrictions

30. Given the Commission's decision to eliminate eligibility requirements, and the fact that broadband is the predominant use of the EBS band, the Commission sees no value in maintaining special lease restrictions that only apply to EBS. Eliminating the leasing restrictions that only apply to EBS licenses will make the rules for the 2.5 GHz band consistent with other Wireless Radio Services, incentivize build-out in rural areas and provide additional flexibility to both EBS licensees and lessees to enter into mutually beneficial arrangements.

31. The Commission agrees with commenters that argue that these lease restrictions are unique to EBS and that they constrain commercial operations and deter investment, particularly in rural areas. The Commission concurs with VIYA that, if eligibility restrictions are eliminated, the restrictions on lease terms serve no purpose.

32. The Commission acknowledges that many educational institutions oppose eliminating restrictions on lease terms, with a split between educational institutions that support the current leasing rules and those that want to impose additional restrictions on leasing. Supporters of the current leasing rules argue that the lease term limitations allow educational institutions to review their leases periodically in light of changing needs and technology. In contrast, Educational Broadband Corp. (EBC) urges the Commission to eliminate lease terms that transfer too much control to the lessee, while Havasupai and Utah would prohibit leasing to commercial providers so that use of the spectrum can be focused on education. The Commission agrees with those commenters arguing that its actions should not harm or invalidate existing leases, and the Commission emphasizes that nothing in this *Report and Order* is intended to invalidate existing lease provisions. Leases are a form of contract, and the parties retain the ability to exercise their rights under state contract law. Indeed, there is broad agreement among both educational institutions and commercial providers that the Commission should not take any action to invalidate or harm existing leases. As HITN writes, ''[b]oth commercial lessees and educational lessors, have invested in services and equipment, in substantial reliance on the negotiated terms of their existing leases, and the Commission should make no rule changes that would interfere with or substantially alter such contractual rights and obligations.'' WCAI and Sprint take a similar view. To the extent some argue for additional restrictions on leasing, the Commission finds that such additional restrictions would be inconsistent with its goals of promoting broadband deployment using EBS spectrum and maximizing flexibility for EBS licensees.

33. The Commission therefore eliminates § 27.1214 of the Commission's rules, except for paragraph (d). In addition, the Commission will eliminate § 1.9047, which is a cross-reference in the secondary market rules to § 27.1214.

4. Modifying Existing License Areas

34. To ensure that the fallow spectrum in this band is made available for use quickly, the Commission has decided to leave existing license boundaries for incumbent 2.5 GHz licenses intact, rather than imposing a complex and protracted rationalization process on incumbents. In the *NPRM,* the Commission proposed to rationalize the current point-and-radius license areas held by incumbents to a defined geographic area and sought comment on a number of issues related to this proposal. Upon review of the record, however, and in light of the unique circumstances posed by licensing of this 2.5 GHz band as discussed below, the Commission finds that engaging in the complex, and potentially confusing process of rationalizing current licenses to a geographic area (such as counties or census tracts) would delay making the white spaces available in this band and would not likely result in the potential benefits explored in the *NPRM.*

35. With regard to the *NPRM*'s proposal to modify each existing license to include all of the census tracts covered by each current geographic service area the Commission is persuaded by opponents' argument that census tract-based rationalization would not necessarily result in more easily-determined license boundaries and therefore would not facilitate service by either existing licensees or new entrants. As the EBC and other commenters point out, any method of assigning census tracts to incumbents is likely to leave license areas with edges like ''saw teeth''—irregular zig-zagging

lines with frequent, small protrusions. Given the propagation characteristics of the 2.5 GHz band, it would be difficult to provide services to these areas as a technical matter, and this difficulty may result in significant degradation of service near market boundaries, as each licensee decreased power in order to remain within power limits, resulting in lower signal strength and lower service quality in the area. This issue does not arise to the same degree with the current license areas, as their smooth, circular contours are more consistent with signal propagation patterns. In addition, any problems caused by these irregular boundaries necessarily also would affect the white space available for licensing subject to competitive bidding, at the borders between incumbents and new entrants. Because the potential for operational problems far outweighs the small potential for improvement in the regularity of the resulting white space, the Commission therefore declines to adopt a census tract-based rationalization scheme.

36. The Commission also rejects the proposal by commenters to expand existing GSAs to include the counties covered by or that intersect the geographic service area, based on a coverage threshold determined by the percentage of the geographic area of the county covered by the licensee. While the Commission has recognized the benefits of adopting county-based licensing in other bands, the Commission declines to adopt a county boundary-based rationalization scheme for incumbents in the 2.5 GHz band for several reasons. First, the Commission is concerned about the potential for some licensees to receive a much larger GSA, with no corresponding requirement to provide service in the expanded area. For example, San Bernardino County, the largest county in the United States, covers over 20,000 square miles, compared to the maximum incumbent license area of approximately 3,850 square miles. Since the Commission is not applying updated performance requirements to existing EBS licenses, there is no guarantee that existing licensees would use the expanded area. Alternatively, was the Commission to adopt NACEPF's suggestion to expand incumbents' licenses to county boundaries subject to additional build-out requirements, incumbents with no interest in serving additional geographic areas, especially in very large counties, could ultimately lose their entire license based on a failure to expand service.

37. Second, implementing county-based expansion in situations with multiple incumbent licenses in the same county raises complex issues that likely reduce significantly the benefits of county expansion. To handle such situations, several commenters suggest ''splitting the football,'' the methodology that the Commission previously employed in this band to address the issue of overlapping circular GSAs or alternative methods to deal with multiple incumbents expanding into the same county. While ''splitting the football,'' or using a similar method to establish a border between multiple incumbents expanding into the same county, might be equitable for current licensees, it would not result in regular, mappable license areas based on geographic boundaries. The resulting borders would not correspond to any official boundaries or natural features; instead, they could only be calculated by referencing the previous license areas—either the ''point'' of the point-and-radius GSA, or the edge of the previously-calculated circle—neither of which would be immediately visible after rationalization. All of the problems cited by commenters, including the difficulty of administering these arbitrary license areas in ULS, would persist. CA K–12 HSN's suggestion of splitting counties by spectrum is also problematic. Wider channel width is important for many advanced wireless applications, including 5G, and dividing spectrum among multiple incumbents may reduce its usefulness significantly.

38. Third, using a percentage threshold based on existing geographic area coverage of a county relative to the total area of the county limits the amount of rationalization that actually takes place. Commenters originally proposed a wide array of threshold levels of geographic coverage within a county that an incumbent licensee would be required to meet to qualify for expansion to the county's boundaries, including 10%, 20%, 30%, 35%, or 80% of the geographic area of the license. Sprint, WISPA, MidCo, WCAI, CTN, NEBSA, Voqal, and NACEPF subsequently agreed on using a 25% threshold. To the extent the Commission adopted any threshold for county-based expansion, however, many incumbent licenses would remain at least partially ''un-rationalized,'' because if the GSA is in more than one county (as many are), some sections of the license would expand to county borders and some sections of the license would not expand to county borders, but rather would remain bounded by the circle arc. Counties with un-rationalized license sections still would be subject to all the problems and continuing coverage gaps cited in the record. In addition, as WCAI notes, expanding licenses to county boundaries in some cases, while leaving vestigial circle arcs in other counties, *with respect to the same GSA license,* would result in ''significant confusion as to what areas are white space,'' as well as ''exacerbat[ing] the [current] problem by adding a second, geographic area-based approach.''

39. Although some commenters point to certain alleged advantages of county-based rationalization, including eliminating coverage gaps between current license areas better aligning licenses with typical school districts, and other claimed advantages, the Commission concludes that the problems associated with county-based rationalization outlined above outweigh any of these potential benefits. NACEPF also mentions faster 5G deployment in the 2.5 GHz band as a benefit of county expansion, primarily due to the resulting increase in the license areas available to Sprint. While Sprint supports county-based rationalization, it does not make any commitments to deploy in expanded license areas.

40. The Commission also rejects other alternative rationalization schemes suggested by commenters, such as self-defined GSAs, GSAs based on granular population data, or GSAs that vary from state to state based on local school district size. Those methods of rationalizing licenses would be both unpredictable and difficult to implement. The Commission also rejects rationalization of existing EBS licenses to ''correspond with the geographic areas where existing licensees currently provide service,'' because such an approach: (1) Would take years to implement, as it would require an extensive analysis of where service was being provided, (2) would be prone to litigation, and (3) would be inconsistent with the goal of quickly getting unused spectrum into the hands of those who will provide service, including 5G, to Americans across the country.

41. Similarly, any of the rationalization schemes described in the *NPRM* or suggested by commenters would require considerable time to implement and would have to be completed before any auction of remaining spectrum could take place. In addition to the necessary changes to the licensing system, the process of resolving whether the required threshold had been met and dealing with situations where multiple incumbents met the threshold would be complex. Adding a complicated and lengthy rationalization process before the auction could delay the deployment of 2.5 GHz services in currently unlicensed areas. In the interest of

expeditiously moving this important mid-band spectrum into the hands of those best able to develop it, the Commission concludes that the likelihood of considerable delay for such a limited result is not in the public interest.

42. Given the complications and drawbacks inherent in all the rationalization schemes proposed in the record with respect to licensing of this band, the Commission declines to adopt any of the proposals. Instead, the Commission concludes that the best mechanism of putting unassigned spectrum to use as quickly and efficiently as possible is to offer overlay licenses subject to competitive bidding. Such an overlay license approach also addresses any concerns regarding irregular gaps between license areas, allowing overlay licensees to take existing EBS license contours into account when bidding for such license.

B. Local Priority Filing Windows

43. In the *NPRM,* the Commission proposed to use geographic area licensing to assign the remaining unassigned portions of the 2.5 GHz band. Envisioning that these geographic licenses would be assigned by auction, the Commission also sought comment on whether it first should open up to three priority filing windows to give Tribal Nations, other non-licensee educational institutions, and existing licensees an opportunity to file applications for 2.5 GHz licenses to serve their local communities, in advance of any auction for these frequencies. The Commission explained that, in each filing window, qualifying applicants would have the opportunity to apply for one or more vacant channels of EBS spectrum in areas where the applicant can demonstrate that it has a local presence.

44. In this *Report and Order,* the Commission adopts a priority window for Tribal Nations to obtain access to the 2.5 GHz band on rural Tribal lands. The priority window will operate as an overlay license, with Tribal priority window applicants obtaining geographic area licenses subject to protecting incumbent operations within the relevant geographic area. The Commission declines to adopt priority windows for non-incumbent educational institutions or incumbent licensees.

1. Tribal Priority Window

45. The Commission finds that adoption of a Tribal priority window for Tribal entities to obtain EBS licenses on Tribal lands that are located in rural areas is in the public interest. Consistent with the Commission's suggestion in the *NPRM,* the Commission concludes that opening a priority filing window for rural Tribal Nations will provide Tribal Nations with an opportunity to obtain unassigned EBS spectrum to address the communications needs of their communities and of residents on rural Tribal lands, including the deployment of advanced wireless services to unserved or underserved areas. The Commission has recognized that ''members of federally-recognized American Indian Tribes and Alaska Native Villages and other residents of Tribal lands have lacked meaningful access to wired and wireless communications services.'' The EBS spectrum offers sufficient bandwidth to give rural Tribal entities an opportunity to provide broadband wireless service. As proposed in the *NPRM,* applicants in the Tribal priority window will be able to acquire all available EBS spectrum on their rural Tribal lands.

46. The Commission's decision to adopt a Tribal priority window finds broad support in the record, including from many Tribal and Tribal-related commenters, who argue that opening a priority filing window for Tribal Nations would provide rural Tribal Nations with a way to obtain spectrum that could be used to provide needed advanced wireless and broadband services. In addition, those commenters who support local priority filing windows in general also support a Tribal priority window. Even among commenters who oppose local priority windows in general WCAI acknowledges a need for a Tribal priority window. The Commission disagrees with MidCo's assertion that priority windows would ''not further any national policy objectives'' because, as explained above, a Tribal priority window would facilitate access to high-speed broadband, including 5G, on rural Tribal lands.

47. *Eligibility.* As proposed in the *NPRM,* eligibility for the Tribal priority window will be limited to federally-recognized American Indian Tribes and Alaska Native Villages on rural Tribal lands. As of September 24, 2018, there were 573 federally-recognized Indian tribes. Federally-recognized Tribes have a government-to-government relationship with the United States and are eligible to receive certain protections, services, and benefits by virtue of their federally-recognized status. While the Commission's rules with respect to Tribal eligibility in various contexts vary somewhat, they universally limit eligibility to those Tribes that are ''federally-recognized,'' so the Commission will do so with respect to the Tribal priority window.

48. The Commission will extend eligibility in the Tribal priority window to communications providers and other entities that provide communications and other services, provided that that they are owned and controlled by federally-recognized Tribes or a consortium of such Tribes. To permit these entities to be eligible to hold EBS licenses and use those licenses to provide broadband service on rural Tribal lands, the Commission will permit those entities and others that are owned and controlled by a federally-recognized Tribe or a consortium of federally-recognized Tribes to participate in the Tribal filing window and to hold EBS licensees.[6] AIHEC requests that the 38 Tribal Colleges and Universities (TCUs) be classified as eligible to apply for available EBS spectrum. To the extent TCUs or other educational entities are owned and controlled by a federally-recognized Tribe or a consortium of federally-recognized Tribes as well as the other requirements the Commission establishes for participation, they would also qualify as applicants in the Tribal priority window.

49. *Tribal Lands.* For purposes of the Tribal filing window, the Commission adopts the broad definition of Tribal lands contained in the Commission's part 54 rules. The Commission does so because, in both the Universal Service and EBS contexts, the Commission is assisting Tribes in obtaining necessary communications services. The Commission declines to adopt the part 73 definitions proposed by some commenters because broadcast definitions were adopted to permit comparison between non-commercial educators applying for broadcast stations, while the part 54 definition has a similar purpose to the Tribal priority window, to encourage provision of broadband service on rural lands.

50. The Commission will include in the Tribal priority window Tribal lands on-reservation in all situations and off-reservation lands in certain situations. Consistent with the Commission's ongoing effort to close the digital divide on rural Tribal lands, the purpose of this filing window is to provide broadband access to Tribal lands that historically have been unserved or underserved. It is important to ensure that entities acquiring spectrum in this window will

[6] Specifically, the provider must be more than 50% owned by one or more federally recognized Tribal Nations or Tribal consortia and actually controlled by one or more federally recognized Tribal Nations or Tribal consortia.

use it to meet the needs of Tribal members.

51. In the *NPRM,* the Commission requested comment on the appropriate geographic area for such licenses and whether county-based or census tract-based license areas might be appropriate. While some commenters support county-based or census tract-based licensing for Tribal entities, most Tribal entities favor a geographic license area that tracks reservation boundaries. In addition, some Tribal entities have members who don't reside on a reservation but live beyond the boundaries of Tribal lands on off-reservation lands. In addition, some federally-recognized tribes do not have reservations at all. These commenters ask that the Commission includes in this priority window licenses that cover ''counties bordering the licensees' reservations'' or counties in which Tribal lands cover some minimum percentage of a county (such as 10%).

52. The Commission agrees with commenters that including off-reservation lands in the Tribal priority window can help promote its goal of facilitating access to wireless service to underserved Tribal populations, and that the Commission must define eligible off-reservation lands in a way that promotes this goal. With respect to including off-reservation land in the Tribal priority window, the Havasupai propose that Tribal entities be licensed on an ''ad hoc'' basis using a variety of criteria such as: The services to be provided, the location of the target recipients, the amount of EBS spectrum that will be used to provide the service, the broadcast or distribution capabilities of the applicant, and the percentage of the target population that will be served by the proposed size of the service area. The Chickasaw Nation suggest that the service area should be based on whether a ''portion of the Tribe's population will be served by licensing that proposed'' service area. Instead of relying on the ''ad-hoc'' processes proposed by Tribes, the Commission will rely on an existing Commission process and designate off-reservation Tribal lands as eligible for the Tribal priority window if they have already been designated (as of the adoption date of this *Report and Order*) as Tribal lands pursuant to the designation process contained in § 54.412 of the universal service rules. The Commission finds that using the existing process would be efficient and facilitate prompt processing of Tribal priority applications. The Commission finds that limiting eligible off-reservation lands as of the adoption date of this *Report and Order* will provide certainty to Tribal applicants and facilitate administration of the Tribal priority window.

53. While Midco may be correct that, in some cases, ''irregularly shaped'' reservation-based Tribal lands will complicate the geographic landscape for EBS licenses awarded through competitive bidding, the Commission does not see this potential complication as a reason not to make all reservation lands available for the Tribal priority window. EBS licensees that acquire their licenses through competitive bidding will have to protect existing EBS licensees, many of which already have irregularly shaped geographic service areas. More importantly, the Commission finds that the need to provide Tribal lands with broadband service outweighs this additional complexity.

54. *Rural.* To be included in the Tribal priority window, the Commission adopts the proposal from the *NPRM* that, in addition to being designated as Tribal Lands, an area must also be rural. The Commission understands that not all Tribes are located in areas that are considered rural and that by limiting eligibility to rural Tribal lands, some tribes may be excluded from the window. However, as the Commission has previously made clear, bringing broadband access to rural Americans is critical to providing them with the same economic, employment, education and civic opportunities that people in urban areas enjoy. Because the problem of access to wireless communications services is most acute in rural areas, and because the purpose of the Tribal priority window should be to promote service to areas that are currently unserved or underserved, the Commission believes that limiting this priority window to rural Tribal lands will provide the most effective and targeted way to achieve the Commission's goal of closing the digital divide in Tribal lands.

55. First, the Commission is not persuaded by the objections raised to limiting the Tribal priority window to rural areas. For example, the Commission disagrees with the assertion that such a limitation is inconsistent with the ''federal government's trust relationship with Indian tribes,'' as that relationship is not limited to rural areas. The Commission is committed to honoring its trust relationship with Tribal Nations through, among other things, policies facilitating broadband deployment on Tribal lands. Individual policies tailored to specific deployment issues, such as increasing access to spectrum over unserved rural areas, positively contribute to this overall effort. Nor is the Commission persuaded that limiting access to rural areas will reduce flexibility for Tribal Nations to use this spectrum, create definitional uncertainty for Tribal Nations, or create separate classes of Tribal governments, which is inconsistent with the intent of Congress. Priority window applicants seeking access to 2.5 GHz spectrum on rural Tribal lands will not be limited in how they use the spectrum; rather they will have the same flexibility as other licensees. Since the Commission is adopting an objective definition of what land will be considered rural, Tribes will be able to determine whether the lands for which they seek licenses are eligible for this window and make the appropriate demonstration.

56. The Commission is, however, persuaded that, in establishing what constitutes rural Tribal lands for purposes of a Tribal priority window, the Commission should set a population limit that is higher than the one the Commission proposed in the *NPRM.* Although in the *NPRM,* the Commission proposed using the definition of rural Tribal lands from the E-rate and Lifeline programs: *i.e.,* Tribal Lands that are not part of ''an urbanized area or urban cluster area with a population equal to or greater than 25,000,'' the Commission notes that, as the Chickasaw Nation asserts, some clusters within historically rural Tribal lands have populations very close to or perhaps just over 25,000. The Commission therefore adopts the proposed definition but modify the population threshold for an urbanized area or urban cluster from 25,000 to 50,000. Therefore, Tribal lands will be considered rural if they are not part of an urbanized area or urban cluster area with a population equal to or greater than 50,000. In this specific instance, the Commission finds that using the population threshold of 50,000 will provide certainty to Tribes in *bona fide* rural areas that they can take advantage of the Tribal priority window while ensuring that the Tribal priority window is appropriately targeted and limited. Some commenters suggest other definitions of rural for the Tribal priority window. The Commission finds that by focusing on areas that are not part of urbanized clusters, as the Commission does in the E-rate and Lifeline programs, the Commission will best target those areas that are most difficult to serve and are therefore likely in greatest need of high-speed broadband service. The Commission finds that using this population limit is consistent with its goal of targeting underserved and unserved Tribal areas.

57. *Local Presence.* The Commission adopts the *NPRM's* proposal to require

that all applicants for the Tribal priority window have a local presence in any area for which they apply. The Commission believes Tribal entities with a local presence better understand the needs of their communities and are better able to serve those needs. Further, there is no opposition to this proposal with respect to Tribal entities, and thus, the Commission will require applicants for the Tribal priority window to demonstrate that they have a local presence in the Tribal land area for which they seek licenses.

58. *Timing.* To ensure that federally-recognized Tribes have access to the maximum amount of unassigned EBS spectrum available on rural Tribal lands, the Commission will open the Tribal priority window before the Commission makes unassigned EBS spectrum generally available to all entities through competitive bidding.

59. *Procedures.* While few commenters address the application process for the Tribal window, several Tribal entities propose a 90-day notice period prior to the opening of the priority filing window with a 60-day window for the filing of applications. In accordance with the process the Commission uses for competitive bidding and with its notice and comment requirements, the Commission directs the Wireless Telecommunications Bureau to announce procedures for the Tribal priority window through one or more Public Notices and other appropriate outreach to potentially eligible Tribal applicants.

60. The Commission rejects Colville's suggestion that the Commission rank applicants eligible for the Tribal window based on a ''tribe's reservation size and location, with the largest, most sparsely populated, and currently least 'wired' reservations receiving top priority.'' The Commission does not believe it necessary to rank Tribal eligibility. The Commission finds it unlikely that applications filed in the Tribal priority window will be mutually exclusive in light of its criteria requiring that: (1) Tribal applicants be federally-recognized; (2) the area to be licensed be based on a Tribe's reservation or qualified off-reservation lands; (3) the area be rural; and (4) the Tribe have a local presence. To the extent that the Commission does receive mutually exclusive applications, the Commission required by statute to subject such applications to competitive bidding.

61. *Other Issues.* Because the Commission is eliminating the educational use requirements for EBS spectrum generally, the Commission finds that it would make little sense to apply those requirements to new Tribal licensees. To that end, the Commission will not impose educational use requirements on the EBS spectrum available in the Tribal filing window.

62. Consistent with the Commission's general decision to eliminate leasing restrictions generally for EBS licenses, the Commission will not impose such restrictions on Tribal licensees' ability to lease spectrum to third parties. According to certain Tribal commenters, doing otherwise might ''impede the Commission's goal of timely and efficient build out in rural areas.'' Tribal entities may not have the ''know-how or resources to build out a broadband network'' and leasing will increase the likelihood that the spectrum is ''used for its highest and best use.'' In addition, the Tribes should be able to lease unused spectrum to ''bring in much needed revenue.'' Although the Commission is generally eliminating restrictions on assignment and transfer of existing EBS licenses, the Commission believes it necessary to impose some restrictions on assignment and transfers of licenses acquired in the Tribal priority window. Because proponents of the Tribal priority window have indicated an urgent need for the spectrum to provide service to underserved tribal communities, the Commission believes it is appropriate to limit, and will accordingly restrict, Tribal licensees' ability to assign or transfer their licenses until after they have met the build-out requirements applicable to these licenses.

63. The Tribal window will include only unassigned EBS spectrum. The Commission rejects suggestions from several Tribal commenters that the Commission permits Tribal entities to apply for already-licensed spectrum.[7] Not only would such an action be beyond the scope of the *NPRM,* but it also would have a substantial effect on existing licenses that are in compliance with the Commission's rules. However, since licenses granted to Tribal entities will be overlay licenses, if an incumbent license that covers rural Tribal lands is cancelled or terminated, any spectrum that becomes available over time will revert to the Tribal licensee. Similarly, Tribal licensees are authorized to lease, partition, or disaggregate their spectrum, including in areas in or near rural Tribal lands. The Commission does not require that incumbent licensees do so, but the Commission encourages those who have holdings covering, or adjacent to, rural Tribal lands to work cooperatively with new Tribal licensees to facilitate deployment of needed service to these areas.

2. Educational Institution Priority Windows

64. The Commission declines to establish a priority filing window for educational institutions, either for educational institutions that do not currently hold EBS licenses or for existing licensees. Adopting a priority window restricted to educational institutions would be at odds with the Commission's other decisions to provide greater flexibility for more providers to make use of the 2.5 GHz band to offer high-speed broadband service to the public. Given the Commission's experience with service deployment to date in EBS, with the vast majority of licensees leasing their spectrum to commercial providers, the Commission believes that making the unassigned EBS spectrum available for flexible use is the best way of getting broadband service deployed to the public more quickly and extensively. While the Commission understands the desire of certain educational institutions to gain additional access to spectrum, the Commission's decision is guided by the goal of facilitating broadband deployment and spectrum use and perpetuating an outdated regulatory regime in this band will not further this goal.

65. If the Commission adopted a priority window open to all educational institutions, it is highly likely that the Commission will receive mutually exclusive applications. Commenters have identified circumstances that raise substantial doubts about the legal authority of certain EBS licensees, particularly public-school districts and local governments, to participate in a spectrum auction. Specifically, commenters claim that a number of states (approximately 36) have adopted Dillon's Rule, which provides that a municipality may exercise only those powers expressly conferred by statute, necessarily or fairly implied by the expressed power in the statute, or essential and not merely convenient.

[7] Several Tribal commenters suggest that the Commission should revoke licenses or mandate disaggregation of spectrum from incumbent EBS licensees with spectrum covering Tribal lands, or that the Commission otherwise should force them to provide service to the Tribal lands or give their spectrum to the Tribal entity. Bad River asks the Commission for a clarification that EBS licenses can be disaggregated. Bad River Comments at 7, n.12. As § 27.15 permits disaggregation for EBS licenses, such clarification is not necessary. However, nothing in that rule mandates such disaggregation. Bad River Comments at 6–7; Chickasaw Nation Reply at 3; Mural Net Comments at 4; Nez Perce Comments at 3, 5; Pueblo de Cochiti Reply at 2; Santa Fe Indian School Reply at 2. Colville asks that the Commission reassign incumbent EBS licenses that are not being used by the incumbent licensee and make them available for application during the filing window. Colville Comments at 5.

Applied to the auction situation, Dillon's Rule may limit the ability of many municipal educational entities, including counties and school districts that hold EBS licenses, from participating in an auction. The Commission notes that no commenter has attempted to show that Dillon's Rule is not an impediment to auction participation.

66. Those problems become important because, under section 309(j) of the Communications Act of 1934, as amended, if mutually exclusive EBS applications are accepted for filing, the Commission must use competitive bidding to resolve the mutual exclusivity. Educational institutions propose various workarounds to address that issue, including using a first-come, first-served filing system, placing strict limits on the number of channels an applicant can apply for, forcing applicants to form consortia, or basing license grants on the number of enrolled students in a service area. These proposals are inconsistent either with the Communications Act's requirement that the Commission use competitive bidding to resolve mutually exclusive applications or with the public interest test applicable to alternatives that avoid mutual exclusivity. Placing strict limits on the number of channels for which an educational institution could apply could constrain severely the capacity any individual educational institution could provide. Finally, choosing between mutually exclusive applicants on a basis other than competitive bidding or requiring applicants that have applied individually to form a joint venture or consortium is plainly inconsistent with the requirement to use competitive bidding.[8]

67. Although EBPARC argues that the use of priority filing windows would quickly put EBS spectrum in the hands of schools and local operator partners that are eager and ready to build out, the Commission does not see a way to avoid the receipt of mutually exclusive applications. And even though SETDA touts the ability of certain educational institutions to provide broadband to unserved and underserved areas, these limited identified examples, among the thousands of EBS licensees, do not persuade us to establish a priority window for all educational institutions. Given the time and effort and delay that would be involved in establishing and running the priority window, and the likelihood that such a window for all educational institutions would result in having to auction the spectrum anyway, the Commission finds that moving directly to flexible use and open eligibility would be the most expeditious method of making spectrum available to provide broadband service in rural and underserved areas, consistent with the Commission's statutory objective to ensure ''the development and rapid deployment of new technologies, products, and services for the benefit of the public, including those residing in rural areas, without administrative or judicial delays. . . .'' The Commission finds that the advantages to the public of making critical mid-band spectrum available for flexible commercial use on a prompt basis far outweigh the detriment to those educational institutions.

68. The Commission recognizes that some institutions have a desire to provide broadband service to rural, underserved areas. In establishing a priority window for Tribal entities—sovereign nations seeking to bring broadband service to the members of their Tribal Nations, but which historically have not had access to such spectrum—but declining to establish a new priority window for educational institutions, the Commission exercising its considered judgment about which proposals will most effectively and expeditiously achieve its statutory obligations and objectives. The Commission believes the Tribal priority window will be a more focused solution than an educational window, since Tribal entities will have a clear incentive to target areas lacking broadband, and Tribes must already work with providers that want to deploy broadband on rural Tribal lands.

69. The Commission has noted that Tribal lands, in comparison to comparable non-Tribal lands (including in rural areas), frequently have characteristics that increase the cost of entry and reduce the profitability of providing service, including cultural and language barriers, a lack of existing infrastructure, and a predominance of low-income residential customers rather than business subscribers. A recent report to Congress on broadband coverage on Tribal lands recognized that there is a considerable gap between Tribal lands and non-Tribal areas in terms of population covered by mobile LTE service. Further, the report noted that people residing on Tribal lands currently have access to fewer providers that offer 4G LTE coverage. In contrast, the fact that a small fraction of educational institutions might be positioned to provide broadband service in rural areas is not a sufficient basis for establishing a general priority window for all eligible educational institutions.

70. Thus, in the context of the federally-recognized Tribes' unique status, their relationship of trust with the Commission, and their right to set their own communications policies, as well as the unique and significant obstacles to offering service in Tribal areas and the fact that they have not previously had access to this spectrum, the Commission concludes that they have an interest in obtaining additional 2.5 GHz spectrum that is greater than and distinguishable from the interests of educational entities. Beyond Tribal areas, the Commission believes that auctioning overlay licenses for remaining white spaces will be a more effective means of addressing the digital divide. Specifically, new EBS licensees will have market incentives to provide service and will also be required to meet new performance requirements.

71. The Commission also notes most rural Tribal lands areas will likely be associated with a single Tribal entity, whereas many localities have a wide variety of educational institutions that could have a local presence. Accordingly, a Tribal priority window is less likely to trigger mutual exclusivity in a significant number of license areas than a priority window for educational institutions (or a priority window that includes Tribal entities and educational institutions).

72. The Commission also does not adopt a priority window for existing licensees. The Commission declines to open a priority window for existing licensees to expand to county boundaries for many of the same reasons that the Commission declines to expand those licensees' footprints to census tract or county boundaries; the Commission expects that such a window would be needlessly complicated and delay the deployment of critical mid-band spectrum. Existing licensees have already had the opportunity to avail themselves of the benefits of EBS spectrum. For this reason, the Commission rejects the recommendations of Bridge the Divide and EBC to open a window for incumbent EBS licensees.

[8] The Commission notes that API has requested that the Commission provide a filing window for critical infrastructure and allow preemptory use of the 2.5 GHz spectrum in certain emergency situations related to oil and gas disasters. API Comments at 3–4. As the Commission determines herein, open eligibility is the best option for assigning unassigned EBS spectrum. API has not demonstrated a critical need for this spectrum and API's members are free to participate in the auction of overlay licenses that the Commission will conduct. *See* section III.C, *infra.*

C. Licensing Areas Containing EBS White Spaces

1. Auction of EBS White Space Licenses

73. As proposed in the *NPRM,* any remaining unassigned EBS spectrum will be made available for commercial use via competitive bidding immediately following the completion of the Tribal priority filing window. Section 309(j) generally requires the Commission to employ competitive bidding to award licenses when mutually exclusive applications have been accepted for filing. With the elimination of the eligibility and educational use requirements, the potential for mutually exclusive applications for unassigned EBS spectrum should increase dramatically. While commenters have suggested various ways to avoid mutual exclusivity, in this case, the Commission finds that accepting mutually exclusive applications and using competitive bidding to resolve the mutual exclusivity is the best way to assign spectrum quickly and efficiently for its highest-valued use. Commercial operators strongly support competitive bidding for unassigned EBS spectrum.

74. The Commission is not persuaded by the educational community's concerns about the use of competitive bidding for unassigned EBS spectrum. First, the Commission rejects claims that assigning licenses by auction will lead to the abandonment of educational services and a worsening of the digital divide. To the contrary, the Commission believes this approach is far more likely to deliver value to educational institutions and to help close the digital divide than the status quo, in which EBS spectrum either has lain fallow or has generally not been used for the purpose of providing educational services. The Commission finds that assigning licenses by auction will not displace or impair existing incumbent licenses or leases, nor will the assignment of overlay licenses impair existing services, since new 2.5 GHz licensees will be required to protect existing incumbent operators from harmful interference. Nothing in this *Report and Order* requires incumbent licensees to abandon their current educational use or to change how they use their spectrum. Finally, the Commission finds that entities that acquire their licenses by auction will have an incentive to provide services to address the digital divide because all new EBS licensees will have to meet the performance requirements that the Commission establishes in this *Report and Order* in markets that they acquire. Licensees, whether incumbent or new, can provide any services the market requires, without limitation.

75. *Auction of Overlay Licenses.* To make the unlicensed EBS spectrum as attractive as possible to potential entrants, while protecting the rights of incumbent EBS licensees and their lessees, the Commission concludes that offering geographic overlay licenses that are subject to competitive bidding in those markets where white spaces (*i.e.,* spectrum that is not associated with an active license) exist is the best mechanism for assigning this spectrum. With overlay licenses, the licensees obtain the rights to geographic area licenses ''overlaid'' on top of the existing incumbent licenses. As with an ordinary flexible use license, the overlay licensee may operate anywhere within its geographic area, subject to protecting the licensed areas (*i.e.,* GSAs) of incumbent licensees. If an incumbent licensee in a county cancels or terminates its license, the overlay licensee obtains the rights to operate in the geographic area and on the channel of the cancelled license. An overlay licensee may clear its geographic area by purchasing the incumbent licenses, but it does not have the exclusive right to negotiate with the incumbent licensee for its spectrum rights or to purchase an incumbent license in the geographic area in which it has the overlay rights. An auction of overlay licenses would make the unassigned EBS spectrum available expeditiously to potential bidders and would provide a mechanism for those bidders to acquire additional spectrum usage rights within their geographic area when and if an incumbent licensee desires to make its spectrum available. For these reasons, the Commission believes that assigning overlay licenses for vacant and available EBS spectrum by competitive bidding is the best method for assigning such spectrum, because it will maximize the potential for expansion, without disrupting existing licensees and lessees.

76. It does not make sense to limit the auction to licenses covering only unlicensed EBS spectrum. Given the large number of existing incumbent EBS geographic service areas, that is 35-mile radius circles, there may not be enough vacant and available EBS spectrum in many markets to encourage competition for those markets in an auction limited to these white space areas. As noted in the *NPRM,* in many markets all that is available are ''small, irregularly shaped areas between GSAs.'' Another factor that may affect interest in licenses that are not overlay licenses, but rather cover vacant and available spectrum only is that, although the total available geographic area of the EBS vacant and available spectrum might be substantial (50%), the percentage of population covered by the vacant and available (slightly over 15%) may not be.

77. Another distinguishing characteristic of the EBS band is the preponderance of leasing by existing EBS incumbent licensees. While there are 2,193 active, regular EBS licenses, there are 2,046 long-term *de facto* control leases involving EBS licenses. The majority of those leases are with Sprint, but there are other lessees in the 2.5 GHz band. These leases are authorized to have terms of up to 30 years and often contain rights of first refusal or purchase options. While one commenter appears to suggest that the Commission considers terminating EBS leases to facilitate transition of the band, the Commission continues to believe that such an action would serve as an undue deterrent to the negotiation of spectrum leasing, in this as well as other bands, ''thus creating uncertainty among all parties that have entered into or are contemplating agreements under the Commission's Secondary Markets rules and policies.'' Thus, the Commission must consider the impact of those leases on a potential auction.

78. The Commission is not persuaded by the objections raised in the record to offering overlay licenses at auction. For example, there is no evidence in the record supporting the allegation that the winning bidders would be motivated ''to undermine existing EBS licenses serving the area, in order to obtain access to that EBS spectrum under the overlay license without having to lease it.'' Moreover, incumbent EBS licensees will retain control over their licenses and the right to protection from interference from the operations of overlay licensees, their lessees, and other successors in interest.

79. Nor is the Commission persuaded by alleged disadvantages of overlay licensees. For example, Voqal asserts that in many, particularly urban and suburban, markets, only slivers of areas are available for new licensing, and that, as a result, there will be ''significant technical complexity engineering a network to operate without impacting adjacent licensees.'' The technical complexities that may result from an auction of overlay licenses are a by-product of its most important advantage, namely the protection of the rights and interests of incumbent licensees. As such, potential bidders will need to consider carefully these technical issues as they decide whether to participate in the auction. Voqal further argues that ''allowing a new buyer to purchase this spectrum would foreclose opportunities

for existing providers to cover these areas just outside the current GSAs, and that this could lead to very different levels of service in the two adjacent GSAs, which could include residents of the same county.'' The Commission notes that overlay licensees will have an incentive to put to use licenses they acquired at auction and also will be required to provide service in order to meet their performance requirements. Proceeding to auction of the vacant and available EBS spectrum will permit market forces to determine the highest and best use of this spectrum.

80. *Incentive Auction.* The Commission finds that conducting an incentive auction could be particularly challenging for purposes of assigning flexible use licenses for EBS white spaces because: (1) The majority of the licensed EBS spectrum is already leased, (2) incumbent EBS licensees and potential bidders have demonstrated little interest in participating in an incentive auction, and (3) many EBS licensees do not have authorization under state law to participate in any kind of auction. Commenters note that such ''[t]wo-sided auctions are complicated, costly to the government as well as to participants, and take a long time to complete;'' moreover, any repacking process would be disruptive for incumbent EBS licensees that wish to continue to provide educational services. The Commission therefore concludes that its policy objectives are better served by assigning overlay licenses subject to auction as described above.

81. Most commenters oppose an incentive auction because the vast majority of EBS spectrum is subject to long-term leases that would preclude most EBS licensees from participating in the reverse auction. They note that an incentive auction would not work from a legal or practical perspective because it would require participation from both existing licensees and their lessees. Further, commenters note that even if the terms of leases permitted licensees to participate in an incentive auction to relinquish their spectrum usage rights, and forward auction participants bid on licenses subject to the existing leases, the prevalence of long-term leases could severely limit bidders' interest in the new licenses offered. Commenters contend that the existence of the leases lessens the likelihood that entities other than the current lessee would bid, and that it would ''badly distort a potential forward auction.''

82. AT&T claims that EBS licensees would be able to participate in an incentive auction, despite existing leases, because they could negotiate a price at which lessees would give up their rights. The Commission expects that it likely would be difficult or impossible for many EBS licensees to pay commercial lessees to break their leases, as most EBS licensees are educational, non-profit entities. Although TechKnowledge suggests that the Commission could invalidate lease provisions that would prevent EBS licensees from participating in an incentive auction, unilaterally modifying contractual provisions agreed to as part of an agreement between a licensee and lessee raises serious questions of fairness and legality. Moreover, even if such lease provisions were invalidated, many EBS licensees may still be unable to participate in an incentive auction because they lack the legal authority under state law to do so.

83. AT&T contends that the majority of entities opposing incentive auctions ''have a powerful self-interest'' in doing so because keeping EBS licensees confined to the secondary market prevents interested parties from knowing the value of the licenses, especially after eligibility and use restrictions are eliminated. While AT&T likely is correct that lessors and lessees have an interest in protecting existing leases, the Commission finds that such an interest is legitimate where they have relied on those leases to build their networks and where such leases have long been permitted under its rules.

84. While there is limited support in the record for an incentive auction as a way to ''encourage incumbents to relinquish voluntarily some or all of their spectrum usage rights,'' the Commission concludes that it can achieve much the same result with less disruption to existing licensees and lessees through an auction of overlay licenses. For example, commenters allege that, if the Commission acts on its proposals to eliminate eligibility restrictions and make EBS licenses readily transferable, an incentive auction will not be necessary to promote the transition of the band to commercial use, since the use of the spectrum is not changing. As WCAI notes, EBS licensees that wish to sell their licenses and have the ability to do so will be able to sell quickly and efficiently, and without administrative costs, via secondary markets, due to the lifting of the eligibility restrictions. In addition, as WCAI explains, not all EBS spectrum is fungible. In these circumstances, given the Commission's decision to eliminate eligibility restrictions, an auction of overlay licenses will quickly assign licenses for EBS white spaces and promote the transition of the band with little disruption to existing users of the spectrum.

85. *Applicability of Part 1 Competitive Bidding Rules.* Substantially consistent with the *NPRM,* the Commission adopts its proposal to conduct any auction of EBS licenses in conformity with the general competitive bidding rules in part 1, subpart Q, including any modifications that the Commission may adopt for its part 1 general competitive bidding rules in the future. The Commission believes that its general competitive bidding rules are suitable to conduct an auction of EBS licenses. The limited comment the Commission received on these issues generally supports use of the general part 1 competitive bidding rules. The Commission believes its part 1 rules will allow market forces to determine its highest and best use, and thus will enable the Commission to meet its goal of spurring more efficient and effective use of the 2.5 GHz band. These rules have proven successful in numerous spectrum auctions and establish an auction process that promotes ''efficient and intensive use'' of this spectrum and the ''development and rapid deployment of new technologies, products, and services for the benefit of the public, including those residing in rural areas,'' and that ''recover[s] for the public . . . a portion of the value of the public spectrum resource made available for commercial use.

86. The Commission will adopt bidding credits for EBS, although the *NPRM* proposed not to apply any designated entity preferences. Based on the Commission's experience with the use of bidding credits in recent spectrum auctions, the Commission now concludes that using bidding credits in competitive bidding for the 2.5 GHz band is an effective tool to achieve its statutory objective of promoting the participation of designated entities in the provision of spectrum-based service. In designing auction rules and procedures, the Commission takes into account both the nature of the service and the nature of the parties most likely to be interested in using the spectrum. Bidding credits have been successful in other auctions, including prior auctions of the 2.5 GHz band. The removal of the eligibility restriction and educational use requirements will attract more commercial operators to the 2.5 GHz band and bidding credits should help to facilitate greater participation in any auction of EBS licenses. The Commission now concludes that offering bidding credits to designated entities, along with the updates to the 2.5 GHz band that the Commission

adopts, strike the appropriate balance and should improve the ability of small businesses to attract the capital necessary to meaningfully participate in an auction of 2.5 GHz spectrum, best satisfying its congressional objectives. The Commission therefore agrees with the comments it received supporting the use of bidding credits in an EBS auction.

87. Consistent with the Commission's other recent auctions, it will adopt the high two of three thresholds in the Commission's standardized schedule of bidding credits for auction of spectrum well suited for 5G deployment. Accordingly, an entity with average annual gross revenues for the preceding five years not exceeding $55 million will qualify as a ''small business,'' while an entity with average annual gross revenues for the preceding five years not exceeding $20 million will qualify as a ''very small business.'' [9] In the *Competitive Bidding Second Memorandum Opinion and Order* (59 FR 44272 (Aug. 26, 1994)), the Commission stated that it would define eligibility requirements for small businesses on a service-specific basis, taking into account the capital requirements and other characteristics of each particular service in establishing the appropriate threshold. While the capital requirements of the services to be deployed in these bands is not yet known, the Commission believes that using these gross revenue thresholds will enhance the ability of small businesses to acquire and retain capital and thereby complete meaningfully at auction. The Commission also believes that these thresholds are not overly inclusive, and prevent designated entity benefits from flowing to entities for which such credits are not necessary. The Commission will provide qualifying ''small businesses'' with a bidding credit of 15% and qualifying ''very small businesses'' with a bidding credit of 25%, consistent with the standardized schedule in part 1 of its rules. The Commission rejects the proposal for the use of three tiers of small business bidding credits because the Commission believes that this two-tiered approach has been successful in the past, and will once again use it.[10] The Commission believes the use of the small business definitions and associated bidding credits set forth in the part 1 bidding credit schedule will provide consistency and predictability for small businesses.[11]

88. The rural service provider bidding credit awards a 15% bidding credit to those servicing predominantly rural areas and that have fewer than 250,000 combined wireless, wireline, broadband and cable subscribers. The Commission will apply the rural service provider bidding credit to auction of EBS licenses in the 2.5 GHz band. The Commission believes that a targeted bidding credit will better enable rural service providers to compete for spectrum licenses at auction and in doing so, will increase the availability of 5G service in rural areas. The comments the Commission received supports the use of the rural service provider bidding credit.

89. The Commission previously adopted a process for establishing a reasonable monetary limit or cap on the amount of bidding credits that an eligible small business or rural service provider may be awarded in any particular auction. It established the parameters to implement a bidding credit cap for future auctions on an auction-by-auction basis. Consistent with the Commission's longstanding approach, the Commission will initiate a public notice process to solicit public input on certain details of auction design and the auction procedures for the auction of EBS licenses. As part of that process, the Commission will solicit public input on the appropriate amount of the bidding credit cap and subsequently establish the cap that will apply for that auction, based on an evaluation of the expected capital requirements presented by the particular spectrum being auctioned and the inventory of licenses to be auctioned.

90. The tribal lands bidding credit program awards a discount to a winning bidder for serving qualifying tribal land that have a wireline telephone subscription rate equal to or less than 85% of the population. The Commission believes that tribal entities involved in the telecommunications industry face unique challenges in participating in spectrum auctions and that the tribal lands bidding credit will promote further deployment and use of spectrum over tribal lands. While the Commission is also adopting a Tribal priority window, the Commission believes the priority window and bidding credit can complement each other and help facilitate service on Tribal lands. No commenters oppose the tribal land bidding credit nor suggest that the tribal lands bidding credit is unnecessary. Accordingly, a winning bidder for a market will be eligible to receive a credit for serving qualifying Tribal lands within that market, provided it complies with the applicable competitive bidding rules.

2. Description of Licenses Being Offered

91. *Geographic Area.* The Commission adopts counties as the appropriate geographic size for new licenses. The Commission finds that a county-based license will afford overlay licensees the flexibility to develop localized services, allow for targeted deployments based on market forces and customer demand, and facilitate access by both smaller and larger providers. As noted by several commenters, counties also ''nest'' into Basic Trading Areas (BTA)s, and thus they are congruent with the current

[9] The standardized schedule of bidding credits provided in § 1.2110(f)(2)(i) defines small businesses based on average gross revenues for the preceding three years. In December 2018, Congress revised the standard set out in the Small Business Act for categorizing a business concern as a ''small business concern,'' by changing the annual average gross receipts benchmark from a three-year period to a five-year period. Thus, as a general matter, a Federal agency cannot propose to categorize a business concern as a ''small business concern'' for Small Business Act purposes unless the size of the concern is based on its annual average gross receipts ''over a period of not less than 5 years.'' 15 U.S.C. 632(a)(2)(C)(ii)(II), as amended by Small Business Runway Extension Act of 2018, Public Law 115–324 (Dec. 17, 2018). The Commission therefore adopts the Small Business Act's revised five-year average gross receipts benchmark for purposes of determining which entities qualify for small business bidding credits. But because the SBA has not yet revised its regulations to update the definition of ''small business concern,'' for purposes of compliance with the Regulatory Flexibility Act, the Commission will continue to use the SBA's current definition of ''small business,'' which is based on a three-year benchmark. *See infra.*

[10] The proposal for the use of three tiers of bidding credits lacks the necessary justification of why a third tier of bidding credits is necessary to enhance the ability of small businesses to acquire and retain the capital necessary to compete meaningfully at auction for EBS licenses. *See Incentive Auction R&O,* 79 FR 48442 (Aug. 15, 2014), 29 FCC Rcd at 6763–64, para. 477. While the Commission previously adopted three tiers of bidding credits for auction of BRS licenses, the Commission has adopted two tiers of bidding credits in the vast majority of service rule proceedings in which it has adopted small business bidding credits. Given the smaller license size of county than the BRS BTA license, and the lack of information on how a third bidding credit is necessary, the Commission believes the two tiers adopted are appropriate.

[11] The Commission directs the Wireless Telecommunications Bureau in conjunction with the Office of Economics and Analytics to seek further comment on the two specific small business standards the Commission adopts for determining an entity's eligibility for small business bidding credits in an auction of unlicensed EBS spectrum. Specifically, the Commission directs WTB in conjunction with OEA to seek comment on defining a ''small business'' as a business with average gross revenues for the preceding five years not exceeding $55 million, and a ''very small business'' as a business with average gross revenues for the preceding five years not exceeding $20 million. The Commission further directs that WTB and OEA should consult with the Small Business Administration and obtain its approval of the adopted small business size standards in advance of any auction of 2.5 GHz EBS white spaces licenses. 15 U.S.C. 632(a)(2)(C); 47 CFR 121.903.

footprint of BRS licensees, creating consistency with the existing BRS licensing framework. As noted by supporters, licensing by county accommodates a wide variety of business models: it enables rural providers to obtain spectrum just in the area that they intend to serve, while allowing larger providers to aggregate spectrum in multiple counties as part of a larger business plan.

92. The Commission rejects the alternative of census tracts as the geographic area licensing unit. The Commission agrees with commenters opposing the use of census tracts that census tracts are extremely numerous and are dynamic in size and location, which makes them difficult to manage and organize. These commenters contend that ''the numerous boundaries make RF containment problematic, a problem that would be exacerbated by the relatively higher field strength limits involved with 2.5 GHz equipment that can operate at hundreds of watts of power.'' Because many census tracts would be smaller than the average coverage area of a single 2.5 GHz base station, the Commission concludes that census tracts would be unworkable.

93. The Commission also finds Sprint's proposal to offer large-area licenses, based on either Partial Economic Areas or BTAs, inferior to basing licenses on counties. While Sprint notes that ''BTA licensing in particular has the benefit of consistency with the existing BRS licensing framework,'' the Commission is not persuaded that consistency with the BRS framework alone warrants adopting a larger license size for EBS spectrum.

94. *Band Plan.* The Commission adopts a band plan that will include three overlay licenses: the first license will include channels A1–A–3, B1–B3, C1–C3 (49.5 megahertz); the second license will include channels D1–D3, the J channels, and channels A4–G4 (50.5 megahertz); and the third license will include channels G1–G3 and the relevant EBS K channels (16.5 megahertz of contiguous spectrum and 1 megahertz of the K channels associated with the G channel group). A group of small rural carriers supports this band plan. By providing applicants the flexibility to bid on three different licenses, the Commission also will provide opportunity for entities of various sizes and spectrum needs to participate in an auction. As commenters note, it is important that wide channel blocks of contiguous spectrum be available because wider blocks are necessary to provide high-speed broadband access. By creating two new wider channel blocks of 49.5 megahertz and 50.5 megahertz of contiguous spectrum, respectively, the Commission has done just that. Moreover, by creating two new licenses of almost equal size while keeping channel groups together, the Commission has made it easier for the new overlay licensees to coordinate with the incumbent EBS licensees.

95. In the *NPRM,* the Commission asked commenters to address the appropriate channel block size for future licensing and to discuss why such a channel block size would serve the public interest, and the Commission received a variety of proposals in response. While some commenters argue that the Commission should license the current middle band segment as a separate license, the Commission concludes that such an approach would be spectrally inefficient. The middle band segment was originally designed for legacy video services, which have virtually disappeared from the band. Licensing the middle band channels separately creates discontinuity, which is ill-suited for wireless broadband use in general and Time Division Duplexing (TDD)—the predominant use of the band currently—in particular. For this reason, while the Commission agrees with WCAI and Sprint that having three different licenses is appropriate, the Commission does not adopt their specific proposed band plans. WCAI suggests licenses for the lower band (A1–3, B1–3, C1–3, D1–3 and the J channels), the middle band (A–G4) and the upper band. (G1–G3 and the K channels), while Sprint proposes three licenses at (1) A1–4 and B1–4, (2) C1–4 and (3) D1–4 and G1–4. The Commission also rejects WISPA's proposal, supported by US Cellular, for four channel blocks, (1) A1–3 and B1–3, (2) C1–3 and (3) D1–3, A4, B4, C,4, D4 and G4 and (4) G1–G3. By creating separate licenses for the lower and middle parts of the band, these proposals would not maximize the 2.5 GHz band's potential to be used for high-speed wireless broadband services. The band plan the Commission adopts will also create two wide channel blocks of almost equal size. The Commission notes that WISPA would find the band plan the Commission adopts acceptable as an alternative, and the Commission also believes the band plan the Commission adopts is responsive to U.S. Cellular's argument that fixed wireless providers generally need 45 megahertz of spectrum to deploy in the 2.5 GHz band.

96. The Commission further finds that the EBS white space discounts from the spectrum screen also should be eliminated. In the NPRM, the Commission sought comment on whether any rule changes adopted here would warrant modification of its treatment of EBS spectrum in the spectrum screen. Although one commenter, opposing revision of the screen, argues that changes are unnecessary, several others support revising the spectrum screen. WCAI, for example, argues that retaining a spectrum screen discount ''based on outdated educational use requirements and eligibility would not reflect the new reality that all EBS spectrum can be used for commercial purposes.'' AT&T similarly argues that changing the EBS spectrum rules and repurposing EBS spectrum would require the Commission to revise the spectrum screen to include all EBS spectrum because the changes would make all EBS spectrum '''used and useful' for the provision of mobile broadband services.''

97. Although the Commission previously excluded 16.5% of EBS spectrum from the spectrum screen to account for the fact that commercial providers did not have an opportunity to gain access to EBS white space spectrum, this discount is no longer necessary. Accordingly, the Commission finds that EBS white space spectrum should be considered ''available,'' for purposes of the spectrum screen.

98. Finally, the Commission concludes that it is no longer necessary to exclude 5% of EBS spectrum from the spectrum screen in light of its decision to eliminate the educational use requirement. While the Commission recognizes that some existing EBS spectrum leases may include terms with educational use restrictions, the Commission believes that if there are such aspects of EBS spectrum leases that warrant further consideration, its case-by-case review of secondary market transactions is the best way to assess the impact of such spectrum lease contractual provisions in particular local markets.

3. Requirements for New 2.5 GHz Licensees

99. *Performance Requirements.* The Commission adopts the performance requirements that the Commission proposed in the *NPRM,* replacing the existing substantial service regime [12]

[12] Currently, licensees in the 2.5 GHz band, including EBS licensees, are subject to a substantial service regime of performance requirements, which were set forth in 2006 as part of the ongoing efforts to transition the band to the new band plan established in 2004. Licensees were required to demonstrate compliance by May 1, 2011. This

Continued

with a menu of specific performance requirements for EBS licensees that depend on the specific service they are offering. Going forward, EBS licensees that are required to make a build-out showing under these new standards may fulfill their final performance requirements by showing any of the following: (1) 80% population coverage for mobile or point-to-multipoint service (50% interim); (2) 40 links per million persons (one link per 25,000) for fixed point-to-point service (20 links per million interim (one link per 50,000)); or (3) 80% population coverage for broadcast service (50% interim). No other types of showing or levels of coverage will be accepted. These benchmarks will apply to both licenses won at auction and licenses granted through the Tribal priority window.

100. These benchmarks are similar to those for the AWS–3 and WCS bands (which have similar propagation characteristics) but are slightly higher (an additional 5%) to account for the maturity of technologies already developed and deployed in the 2.5 GHz band. Specifically, while the AWS–3 and WCS performance requirements were established before there were extensive operations in those bands, there are currently extensive operations and ample equipment in the 2.5 GHz band. These increased requirements will help to address the concerns of some commenters that current licensees of this spectrum are not deploying to all communities within their license areas. This approach to performance requirements is supported by several commenters who advocate for robust performance requirements, including the *NPRM* proposal specifically, as well as other commenters who generally support build-out requirements without providing specifics.

101. Some commenters suggest a more relaxed approach to performance requirements, including retaining the current substantial service regime. Other commenters support adoption of the same performance requirements as those currently applicable to BRS licensees, which are similar to the current EBS substantial service standard. The Commission rejects retaining the existing substantial service requirement for new EBS licenses, as the existing requirements are inconsistent with the build-out requirements the Commission has adopted for similar bands such as AWS. The Commission agrees with WISPA that those substantial service standards are too vague, particularly in the context of a band that has a developed equipment ecosystem. The existing substantial service requirements were adopted prior to the transition to the new band plan and at a time when there was substantial uncertainty about how the band would be used in the future. Now, the ability to use EBS for broadband is well established. Given the maturity of the ecosystem in this band, and the low thresholds and vague requirements of the previous standards, the Commission declines to continue with the substantial service regime or to adopt any minor modification thereof. In other bands, the Commission has determined that a substantial service regime, which lacks firm minimum requirements, does not adequately safeguard effective use of the relevant spectrum, and the Commission extends that conclusion to EBS. The increased requirements the Commission adopts in this *Report and Order* will address that concern more effectively than the current requirements.

102. A few commenters suggest alternatives to the *NPRM* proposal beyond retention of substantial service. The Nez Perce Tribe suggests that the ''coverage target'' should be 100% area coverage, but that the actual benchmark should be determined by each licensee according to the specific terrain and circumstances of each license. Other commenters propose imposing various standards of service, such as speed or affordability, as part of the performance requirement. The Commission declines to incorporate these concepts into the new performance requirements the Commission adopts. The Nez Perce Tribe's case-by-case suggestion would result in requirements that would vary across licenses, and that, if based on a licensee's own analysis, could not be determined prior to auction. The resulting uncertainty would be unfair to auction participants, who could not reasonably anticipate the construction obligation that would accompany their new licenses. This system also would place a significant burden on licensees to justify their particular level of construction as adequate in their circumstances, rather than giving licensees a set benchmark on which to rely. The Commission also declines to incorporate any quality of service measure into the performance requirements. The Commission does not include such a requirement in any other wireless service as a condition of license renewal, and the commenters suggesting it have not provided evidence that EBS as a service is uniquely situated so as to require it.

103. The Commission declines to adopt any educational use metric for performance requirements. The potential for wireless services to support education is clear; nevertheless, this goal will be supported best by adopting stringent build-out requirements that encourage wider deployment of all broadband services, rather than by attempting to define what constitutes acceptable levels or types of educational use specifically. The few comments received on this issue illustrate the difficulty of finding a specific educational metric that encourages deployment without placing an undue regulatory burden on licensees. The robust mobile, fixed, and broadcast metrics the Commission adopts in this *Report and Order* will promote deployment of wireless services that can be used for all purposes, including education. The Commission recognizes that incumbent licensees may have relied on the educational use standard to fulfill their performance requirements in the past. Those licensees may continue to use the substantial service standard in order to make their renewal showing, but the substantial service standard, including the educational safe harbor, will not be available to new licensees in the band.

104. The Commission also sought comment in the *NPRM* on the appropriate timeline for the interim benchmark, and the appropriate penalty for failure to meet a benchmark. In this regard, the Commission will apply the interim benchmark after four years, and the final benchmark after eight years. The penalty for failure to meet the interim benchmark will be the acceleration of the final benchmark deadline by two years, to six years rather than eight. This timeline is slightly more aggressive than WISPA's suggestion of a five-year interim and a ten-year final deadline, but the critical role of mid-band spectrum in today's spectrum environment warrants such an approach. The existing ecosystem of equipment already available in the band, and the success of recipients of waivers and STAs with expeditious deployment, also suggest that a more compressed timeline is appropriate here. This timeline and the two-year acceleration penalty are also largely consistent with the Commission's rules in other bands and will help harmonize the regulatory regime of the 2.5 GHz band with other commercial wireless

requirement includes specific safe harbors, including 30% population coverage for mobile or point-to-multipoint use, six permanent links per million for fixed point-to-point services, and an educational safe harbor for EBS licensees specifically, consisting of 20 hours of educational use per channel, per week. *See BRS/EBS Second R&O,* 71 FR 35178 (June 19, 2006), 21 FCC Rcd at 5719–33, paras. 276–304; *see also BRS/EBS FNPRM,* 69 FR 72048 (Dec. 10, 2004), 19 FCC Rcd at 14282–84, paras. 321–22.

services. Apart from WISPA, no other commenters offer suggestions for the timing of benchmarks or the acceleration penalty.

105. As with other wireless services, a license will automatically terminate if the licensee fails to meet the final construction benchmark. The Commission rejects as unnecessary Midco's suggestion to allow one or two 90-day cure periods in order to accommodate ''difficult conditions'' or ''other unknown impediments.'' The Commission expects applicants to conduct their due diligence and plan to meet these buildout deadlines. In extraordinary circumstances, the Commission may consider waiver requests to accommodate unanticipated difficulties requiring short-term accommodations.

106. For licenses acquired via the Tribal priority window described above, the Commission adopts a different timeline. These licenses must demonstrate compliance with interim build-out levels after two years, and final build-out levels after five years. The penalty for missing the interim deadline will be an acceleration of the final deadline by one year. This timeline will encourage deployment in underserved areas, while discouraging speculation or application mills. The equipment ecosystem in this band has matured considerably since potential licensees last had a routine opportunity to apply for this spectrum, and the cost and difficulty of deployment have eased significantly. Recent recipients of waivers and STAs in this band have been able to deploy and begin service well within a five-year timeframe. This timeline is also consistent with the recommendation from MuralNet, which developed and deployed the network for the Havasupai Tribe.

107. There are also considerations specific to the Tribal window that support this timeline for those licensees. Because Tribal applicants will be able to specify their own service area, this timeline will encourage those applicants to estimate accurately the level of deployment they will be able to achieve, rather than over-claiming and thereby precluding any other potential licensee. The Commission therefore rejects Colville's suggestion that requirements should not be ''more robust'' than for other licensees, and Havasupai's suggestion that Tribes should not be subject to any build-out requirement whatsoever. In addition, a five-year Tribal deployment timeline will enable an auction-based overlay licensee to reclaim unbuilt spectrum before the end of its ten-year overlay license term if a Tribe is unable to build, helping to ensure that the spectrum is put to use.

108. *Renewal Standards.* In 2017, the Commission adopted a unified regulatory framework for the Wireless Radio Services (WRS) that replaced the existing patchwork of service-specific rules regarding renewal, comparative renewal, continuity of service, and partitioning and disaggregation, with clear and consistent rules of the road for WRS licensees. The Commission adopts the *NPRM's* proposal to apply the WRS framework of renewal standards to new EBS licenses, including licenses granted via the Tribal priority window. With the actions the Commission takes to make EBS more flexible and similar to other bands where the WRS rules apply, the Commission finds it is now appropriate to apply the WRS rules to EBS. This change will harmonize the regulatory regime of the 2.5 GHz band with other bands that support commercial wireless services, and it will give licensees more clarity on their regulatory requirements and options, including the flexibility to partition or disaggregate their licenses. The record supports applying the WRS framework to new EBS licensees. The Commission believes that updating the renewal standards in this manner will encourage more rapid deployment of next generation wireless services, including 5G.

109. The Commission also applies the WRS framework to existing EBS licensees.[13] The Commission sought comment on this issue in the *NPRM,* and several commenters support this idea. Applying the renewal standard to existing licenses will ensure that the licensees who hold them will continue to provide some level of service and that the frequencies covered by those licenses do not lie fallow. Consistent with the Commission's treatment of other incumbent licenses that did not have a prior renewal standard, the Commission will require compliance with the renewal standard for renewal applications filed after January 1, 2023.

110. In evaluating existing licensees under these new renewal standards, however, the Commission will apply new WRS build-out standards if the Commission promulgates them.[14] Without prejudging the outcome of that open proceeding, the Commission seeks to harmonize the 2.5 GHz band with other bands that support commercial wireless services, recognizing that this Order transitions the band to more flexible use. For clarity, the Commission emphasizes that the old, substantial service build-out standard contained in § 27.14(o) of the Commission's rules will apply to existing EBS license renewals, unless the Commission alters the WRS build-out standards upon renewal. The Commission further clarifies that, for purposes of meeting the old renewal standard, the educational use safe harbor contained in § 27.14(o)(2) is available only to licensees that meet the old EBS eligibility standard, since that safe harbor was based on service to accredited educational institutions. If such a licensee transfers its license to an entity that does not meet that standard, the new licensee will be required to make future showings using one of the other safe harbor provisions contained in § 27.14(o).

4. Dismissal of Pending Waiver Requests

111. Upon adoption of this *Report and Order,* the Commission will dismiss, without prejudice, any pending applications for new EBS licenses. A freeze on the filing of new EBS applications was instituted in 2003 in conjunction with the Commission's proposing new technical rules and band plan for the 2.5 GHz band. The Commission has granted some waiver requests to permit the filing of applications for new EBS licenses while the freeze remained in place. There are a handful of additional requests for waiver of the EBS freeze currently pending that seek new EBS licenses. Since this *Report and Order* is instituting a new process for the assignment of EBS spectrum, the Commission sees no need to grant requests for waiver of the freeze, and

[13] This includes the WRS discontinuance of service rule, § 1.953 of the Commission's rules. WCAI objects to applying the new WRS discontinuance of service rule to existing licensees, arguing that such a proposal was not made in the *NPRM.* WCAI July 2 *Ex Parte* at 1–2. In seeking comment on applying WRS to EBS, the Commission noted that WRS ''replaced the existing patchwork of service-specific rules regarding renewal, comparative renewal, continuity of service, and partitioning and disaggregation, with clear, consistent rules of the road for WRS licensees.'' *NPRM,* 33 FCC Rcd at 4703, para. 53. Furthermore, in its comments, ''WCA agrees with Commission that it should apply the standard WRS rules for permanent discontinuance and renewal to all 2.5 GHz licensed spectrum, incumbent EBS licenses and any new EBS licenses issued pursuant to this rulemaking.'' WCAI Comments at 32. As for WCAI's alternative request that it defer applying the discontinuance of service rule until January 1, 2021, the Commission finds that its general deferral of the effective date of rules in this proceeding should be sufficient, particularly since the rule will also apply to commercial BRS spectrum in the 2.5 GHz band.

[14] In 2017, the Commission sought comment ''on whether renewal term construction obligations beyond those applicable during a licensee's initial license term would help achieve its goal of increasing the number of Americans with access to wireless communications services.'' *See WRS FNPRM,* 82 FR 41580 (Sept. 1, 2017), 32 FCC Rcd at 8911, para. 100. The WRS FNPRM remains pending.

therefore the Commission dismisses these pending applications without prejudice. The applicants are free to participate in the license assignment processes adopted herein through the Tribal priority window or competitive bidding, as applicable.

D. Cleaning Up the 2.5 GHz Rules

112. Because the transition from the interleaved channel plan under the former ITFS to the new channel plan under BRS and EBS was completed in 2011, the Commission proposed to remove those rule sections that addressed the transition. In light of the fact that the transition has been completed, the Commission finds that the rules are obsolete and no longer necessary, and that elimination of the rules is therefore in the public interest. The Commission also received no comments objecting to the removal of these rules. The Commission therefore adopts its proposal to remove §§ 27.1230 through 27.1239 of its rules.

113. The Commission also received no comments objecting to the Commission's proposal to make non-substantive clarifying amendments to § 27.1206 of its rules. In light of the Commission's decisions to adopt a Tribal priority window with GSAs based on rural Tribal lands, as well as its decision not to rationalize existing licenses, the Commission will amend § 27.1206 to reflect the decisions it has made. The Commission also reorganizes §§ 27.1207, 27.1208, and 27.1209 to place similar subjects together, reduce duplication, and incorporate the rule changes it has adopted for EBS. These changes do not result in any substantive changes for existing BRS or EBS licenses.

114. Several commenters have made proposals that are outside of the scope of the subject proceeding or that have been made moot by the Commission's changes to the EBS band, and thus, the Commission has not addressing those proposals herein.[15]

E. Effective Date of Rule Changes

115. In order to provide applicants in the Tribal priority window with a stable licensing environment unaffected by changes to the band, the Commission will defer the effective date of the rule changes it adopts in this proceeding[16] (other than the rules adopting the Tribal priority window and the construction requirements rule, which will apply to the Tribal priority window) until six months from the date of **Federal Register** publication of this *Report and Order.*

IV. Final Regulatory Flexibility Analysis

A. Need for, and Objectives of, the Report and Order

116. In the *Report and Order,* the Commission takes steps to permit more flexible use of the 2496–2690 MHz (2.5 GHz) band by current Educational Broadband Service (EBS) licensees and to provide new opportunities for EBS eligible entities, Tribal Nations, and commercial entities to obtain unused 2.5 GHz spectrum to facilitate improved access to next generation wireless broadband, including 5G, for both educational and commercial uses. EBS spectrum currently is assigned in geographic areas of various sizes and shapes and is subject to unique use and transfer restrictions. Consistent with the Commission's goal of making additional spectrum available for flexible use, and to promote use of EBS frequencies that have been unassigned for far too long, the Commission takes steps to encourage and facilitate more efficient use of the 2.5 GHz band. These steps are not intended to curtail the spectrum usage rights of existing EBS licensees, nor to annul or disturb existing agreements between such licensees and commercial operators. Additionally, since the process for transitioning Broadband Radio Service (BRS) and EBS licensees to the new band plan was completed in 2011, the Commission eliminates the BRS/EBS transition rules. The Commission believes it is in the public interest to eliminate these regulations that are out of date and no longer necessary.

B. Summary of Significant Issues Raised by Public Comments in Response to the IRFA

117. There were no comments filed that specifically addressed the proposed rules and policies presented in the IRFA.

C. Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

118. Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed rules as a result of those comments.

119. The Chief Counsel did not file comments in response to the proposed rules in this proceeding.

D. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

120. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the rules adopted herein. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.'' A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

121. *Small Businesses, Small Organizations, Small Governmental Jurisdictions.* The Commission's actions, over time, may affect small entities that are not easily categorized at present. The Commission therefore describes here, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the SBA's Office of Advocacy, in general a small business is

[15] For example, EIBASS and NAB request that the Commission makes clear that EBS licensees are obligated to protect BAS stations in the 2483.5–2500 MHz band. NAB Comments at 1–2; EIBASS Reply at 2. EBS spectrum starts at 2502 MHz and is not adjacent to BAS spectrum. Nothing in the *NPRM* proposes changes to the technical or operational rules. Thus, there is nothing in this *NPRM* that would impact BAS stations and what EIBASS and NAB request is outside the scope of this proceeding. In addition, some commenters request that the Commissions make changes to the E-Rate program in ways that would assist educators and students. *See, e.g.,* Midco Comments at 13–14; SETDA Comments at 9–10; Utah Comments at 4; WCAI Comments at 18–19. Nothing in the *NPRM* proposed any changes to the E-Rate program. Other commenters ask that the Commission adopts new rules-such as imposing a local presence requirement on existing EBS licensees, SETDA Comments at 7, or instituting new procedures for renewal or lease approval processes for EBS licensees. Utah Comments at 2–6. With the elimination of the eligibility and educational use requirements, the Commission sees no reason to address these requests, as they are now moot. VIYA asks that the Commission automatically provides entities providing service via special temporary authority (STA) with full licenses based on their outlay of resources. VIYA Comments at 9–12. The Commission notes that VIYA's subsidiary Choice Communications has filed an application for permanent authority for the frequencies in questions. *See* File No. 0008700428 (filed June 18, 2019). The *NPRM* did not propose this, and the Commission believes this issue is better addressed in the context of Choice's pending application. Accordingly, the Commission will not address this issue in the rulemaking.

[16] The Commission also defers the modification of the spectrum screen until six months from the date of **Federal Register** publication.

an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States which translates to 28.8 million businesses.

122. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of August 2016, there were approximately 356,494 small organizations based on registration and tax data filed by nonprofits with the Internal Revenue Service (IRS).

123. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2012 Census of Governments indicate that there were 90,056 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States. Of this number there were 37, 132 General purpose governments (county, municipal and town or township) with populations of less than 50,000 and 12,184 Special purpose governments (independent school districts and special districts) with populations of less than 50,000. The 2012 U.S. Census Bureau data for most types of governments in the local government category show that the majority of these governments have populations of less than 50,000. Based on this data, the Commission estimates that at least 49,316 local government jurisdictions fall in the category of ''small governmental jurisdictions.''

124. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The appropriate size standard under SBA rules is that such a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census Bureau data for 2012 show that there were 967 firms that operated for the entire year. Of this total, 955 firms had employment of 999 or fewer employees and 12 had employment of 1,000 employees or more. Thus, under this category and the associated size standard, the Commission estimates that the majority of wireless telecommunications carriers (except satellite) are small entities.

125. *Broadband Radio Service and Educational Broadband Service.* Broadband Radio Service (BRS) systems, previously referred to as Multipoint Distribution Service (MDS) and Multichannel Multipoint Distribution Service (MMDS) systems, and ''wireless cable,'' transmit video programming to subscribers and provide two-way high-speed data operations using the microwave frequencies of the BRS and Educational Broadband Service (EBS) (previously referred to as the Instructional Television Fixed Service (ITFS)).

126. *BRS.* In connection with the 1996 BRS auction, the Commission established a small business size standard as an entity that had annual average gross revenues of no more than $40 million in the previous three calendar years. The BRS auctions resulted in 67 successful bidders obtaining licensing opportunities for 493 Basic Trading Areas (BTAs). Of the 67 auction winners, 61 met the definition of a small business. BRS also includes licensees of stations authorized prior to the auction. At this time, the Commission estimates that of the 61 small business BRS auction winners, 48 remain small business licensees. In addition to the 48 small businesses that hold BTA authorizations, there are approximately 86 incumbent BRS licensees that are considered small entities (18 incumbent BRS licensees do not meet the small business size standard). After adding the number of small business auction licensees to the number of incumbent licensees not already counted, there are currently approximately 133 BRS licensees that are defined as small businesses under either the SBA or the Commission's rules.

127. In 2009, the Commission conducted Auction 86, the sale of 78 licenses in the BRS areas. The Commission offered three levels of bidding credits: (i) A bidder with attributed average annual gross revenues that exceed $15 million and do not exceed $40 million for the preceding three years (small business) received a 15% discount on its winning bid; (ii) a bidder with attributed average annual gross revenues that exceed $3 million and do not exceed $15 million for the preceding three years (very small business) received a 25% discount on its winning bid; and (iii) a bidder with attributed average annual gross revenues that do not exceed $3 million for the preceding three years (entrepreneur) received a 35% discount on its winning bid. Auction 86 concluded in 2009 with the sale of 61 licenses. Of the ten winning bidders, two bidders that claimed small business status won 4 licenses; one bidder that claimed very small business status won three licenses; and two bidders that claimed entrepreneur status won six licenses.

128. *EBS.* Educational Broadband Service has been included within the broad economic census category and SBA size standard for Wired Telecommunications Carriers since 2007. Wired Telecommunications Carriers are comprised of establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies.'' The SBA's small business size standard for this category is all such firms having 1,500 or fewer employees. U.S. Census Bureau data for 2012 show that there were 3,117 firms that operated that year. Of this total, 3,083 operated with fewer than 1,000 employees. Thus, under this size standard, the majority of firms in this industry can be considered small.

129. In addition to U.S. Census Bureau data, the Commission's Universal Licensing System indicates that as of March 2019 there are 1,300 licensees holding over 2,190 active EBS licenses. The Commission estimates that of these 2,190 licenses, the majority are held by non-profit educational institutions and school districts, which are by statute defined as small businesses.

E. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

130. The Commission expects the rules adopted in the *Report and Order* will impose new or additional reporting or recordkeeping and/or other compliance obligations on small entities as well as other applicants and licensees. The Commission is not in a position to determine whether the adopted rule changes will require small entities to hire attorneys, engineers, consultants, or other professionals, and cannot quantify the cost of compliance with these rule changes. The Commission does not believe however, that the costs of compliance or the administrative requirements associated with any of the rule changes will unduly burden small entities. The Commission notes that several of the rule changes are consistent with and mirror existing policies and requirements used in similar spectrum

bands. Therefore, small entities with existing licenses in may already be familiar with such policies and requirements and have the processes and procedures in place to facilitate compliance resulting in minimal incremental costs to comply with the *Report and Order.*

F. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

131. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.

132. The Commission does not believe that the rule changes adopted in the *Report and Order* will have a significant economic impact on small entities. The proposed changes expanding the use of the 2.5 GHz band will benefit small entities as well as entities of other sizes by reducing unnecessary regulatory burdens on licensees, promoting greater spectrum efficiency, and facilitating the full use of EBS spectrum to provide advanced mobile broadband services, particularly in rural areas where this spectrum currently sits idle. Moreover, the adopted reforms will permit more flexible use of this spectrum by small and other sized entities that currently hold EBS licenses and will provide new opportunities for EBS eligible entities, Tribal Nations, and commercial entities to obtain unused 2.5 GHz spectrum to facilitate improved access to next generation wireless broadband, including 5G, for both educational and commercial uses. The Commission discusses the alternatives considered to the rules adopted below.

133. *Rationalizing the GSAs of incumbent EBS Licensees.* In the *NPRM,* the Commission proposed to rationalize the current point-and-radius license areas held by incumbents to a defined geographic area. There was both support for this approach and alternatives proposed by commenters. The alternatives considered by the Commission included expansion to county borders, using self-defined GSAs, GSAs based on granular population data, and rationalization but not any expansion of geographic area coverage. Finding the benefits, the Commission believed would result from its *NPRM* proposals are unlikely to materialize to any significant degree, and the process of rationalizing licenses is likely to be complex, time-consuming, and potentially confusing to incumbent and future licensees, the Commission declined to adopt any rationalization scheme for incumbent EBS licenses and left the existing license boundaries intact.

134. *Additional Flexibility for EBS Licensees.* The Commission adopted the *NPRM's* proposal to eliminate the EBS eligibility requirements contained in § 27.1201 of the rules for incumbent EBS licenses, including licenses granted via waiver instead of maintaining the current requirements. This alternative allows the Commission to bring these licenses into better alignment with the flexible use licensing policies used in similar spectrum bands, which feature open eligibility absent a compelling showing that regulatory intervention to exclude potential participants is necessary and has been an effective means of promoting more efficient and better use of the 2.5 GHz band. Small entities should benefit from this increased flexibility to assign or transfer control of their licenses to entities that are not EBS-eligible. The Commission believes that, at this point in time, licensees are in the best position to determine how to use their licenses, or, alternatively, whether to transfer their licenses to a third party in the secondary market.

135. The Commission also eliminated the educational use requirement contained in § 27.1203 of the rules as proposed in the *NPRM* after considering alternative proposals to revise and/or update the requirements to reflect the current broadband use of the spectrum. In doing so the Commission did not find that any these alternatives would facilitate broadband deployment or be workable for licensees or commercial operators. Additionally, after considering alternative proposals to maintain and increase restriction on lease terms, the Commission adopted the *NPRM's* proposal to eliminate restrictions on EBS leases entered into under its secondary markets policies on a going forward basis which will make the rules for the 2.5 GHz band consistent with other part 27 services, incentivize build-out in rural areas, and provide additional flexibility to both EBS licensees and lessees.

136. *Local Priority Filing Window.* The Commission adopted a Tribal priority window for Tribal entities to obtain 2.5 GHz licenses on Tribal lands that are located in rural areas as proposed in the *NPRM,* enabling these entities to acquire all available EBS spectrum on their Tribal lands. This window will allow Tribal entities to address the educational and communication needs of their communities and provide much needed services such advanced wireless services, in areas that are devoid of such services. Conversely, after considering the priority filing window option for existing EBS licensees and for educational institutions that do not currently hold any EBS licenses, the Commission declined to adopt these windows based on a belief that windows for these entities are not the best way to achieve rapid expansion and deployment of broadband in the band.

137. *Licensing of White Spaces.* As proposed in the *NPRM,* the Commission will use competitive bidding to resolve mutually exclusive applications for the unassigned EBS spectrum after the completion of the rural Tribal priority window, finding the competitive bidding alternative is consistent with the other changes made in the *Report and Order* to align EBS licenses more closely with flexible use service rules. An overlay auction was determined to be the best mechanism for assigning EBS spectrum due to, among other things, the costly nature of an incentive auction to government and other participants. Thus, the overlay auction should help minimize participation costs for small entities.

138. The procedures the Commission has adopted contain provisions to assist small entities in competitive bidding. The Commission will employ the part 1 rules governing competitive bidding design, designated entity preferences, unjust enrichment, application and payment procedures, reporting requirements, and the prohibition on certain communications between auction applicants. Furthermore, qualifying ''small businesses''—those with gross revenues for the preceding five years not exceeding $55 million—will be provided with a bidding credit of 15%, and ''very small businesses''—those with average annual gross revenues for the preceding five years not exceeding $20 million—with a bidding credit of 25%. Providing small businesses and very small businesses with bidding credits will provide an economic benefit to small entities by making it easier for small entities to acquire spectrum or access to spectrum in these bands.

139. *Geographic Area and the Band Plan for New Licenses.* The band plan adopted in the *Report and Order* will include three overlay licenses—the first license will include channels A1–A–3, B1–B3, C1–C3 (49.5 MHz); the second license will include channels D1–D3, the J channels, and channels A4–G4 (50.5 MHz); and the third license channels G1–G3 and the relevant EBS K channels (16.5 megahertz of contiguous spectrum and 1 megahertz of the K channel associated with the G channel group). This arrangement will give applicants two wide blocks and one small block from which to choose, providing opportunity for small entities participate as well as medium and large entities with different needs.

140. *Requirements for New 2.5 GHz Licenses.* Regarding performance requirements, the alternatives considered by the Commission were broadly speaking, robust requirements (including the Commission's proposal), relaxed requirements (including the current substantial service standard), or the general concept of a build-out requirement without specifics. The Commission adopted the robust mobile, fixed and broadcast performance requirement metrics from the *NPRM* for new licensees in the band, which will promote the deployment of wireless services for multiple purposes including education. With respect to the timeline for evaluating build-out, the Commission required that the interim benchmark be applied after four years, and that the penalty for failure to make this showing be the acceleration of the final benchmark deadline to six years, rather than eight years. This approach is largely consistent with the Commission's rules for other bands and will help harmonize the regulatory regime of the 2.5 GHz band with other commercial wireless services. Additionally, the Commission will apply the Wireless Radio Services (WRS) framework of renewal standards to both new and existing EBS licensees. The Commission anticipates that updating the performance requirements in this manner will encourage rapid deployment of next generation wireless services, including 5G, which will benefit small entities and the industry as a whole.

141. *Pending Waiver Requests and Cleaning Up the 2.5 GHz Rules.* Small entities should benefit from the Commission's removal of the filing freeze for new EBS licenses, which will provide them greater opportunity to obtain EBS spectrum to meet the needs of their communities. In conjunction with removing the filing freeze, the Commission will dismiss three pending requests to waive the freeze for new EBS licenses. Small entities should also benefit from the Commission's clean-up of the 2.5 GHz rules by eliminating the BRS/EBS transition rules which were completed in 2011 and making non-substantive, clarifying amendments to § 27.1206, making it is easier to understand.

V. Ordering Clauses

142. Accordingly, *it is ordered,* pursuant to sections 1, 2, 3, 4, 5, 7, 301, 302, 303, 304, 307, 309, and 310 of the Communications Act of 1934, 47 U.S.C. 151, 152, 153, 154, 155, 157, 301, 302a, 303, 304, 307, 309, and 310, and section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302, that this *Report and Order is hereby adopted.*

143. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this *Report and Order,* including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

144. *It is further ordered* that the rules and requirements adopted herein *will become effective* six months from the date of publication in the **Federal Register** with the exception of §§ 27.14(u) and (v) and 27.1204 of the rules, which contain new or modified information collection requirements that require review by the OMB under the PRA. The Commission directs the Bureau to announce the compliance date for those information collections in a document published in the **Federal Register** after OMB approval and directs the Bureau to cause §§ 27.14 and 27.1204 to be revised accordingly.

145. *It is further ordered,* pursuant to sections 4(i) and 309 of the Communications Act of 1934, 47 U.S.C. 154(i), 309, and § 1.934(d)(2) of the Commission's Rules, 47 CFR 1.934(d)(2), that the requests for waiver of the freeze on the filing of new EBS applications filed by Monterey Peninsula Unified School District and the Duckwater Shoshone Tribe *are denied,* and the applications filed by Monterey Peninsula Unified School District (File No. 0007664266) and Duckwater Shoshone Tribe (File Nos. 0007768145 and 0007768146) *are dismissed without prejudice.*

List of Subjects in 47 CFR Parts 1 and 27

Administrative practice and procedure, Communications common carriers.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 1 and 27 as follows:

PART 1—PRACTICE AND PROCEDURE

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

Authority: 47 U.S.C. chs. 2, 5, 9, 13; 28 U.S.C. 2461, unless otherwise noted.

■ 2. Amend § 1.907 by revising the definition of ''Covered Geographic Licenses'' to read as follows:

§ 1.907 Definitions.

* * * * *

Covered geographic licenses. Covered geographic licenses consist of the following services: 1.4 GHz Service (part 27, subpart I, of this chapter); 1.6 GHz Service (part 27, subpart J); 24 GHz Service and Digital Electronic Message Services (part 101, subpart G, of this chapter); 218–219 MHz Service (part 95, subpart F, of this chapter); 220–222 MHz Service, excluding public safety licenses (part 90, subpart T, of this chapter); 600 MHz Service (part 27, subpart N); 700 MHz Commercial Services (part 27, subparts F and H); 700 MHz Guard Band Service (part 27, subpart G); 800 MHz Specialized Mobile Radio Service (part 90, subpart S); 900 MHz Specialized Mobile Radio Service (part 90, subpart S); Advanced Wireless Services (part 27, subparts K and L); Air-Ground Radiotelephone Service (Commercial Aviation) (part 22, subpart G, of this chapter); Broadband Personal Communications Service (part 24, subpart E, of this chapter); Broadband Radio Service (part 27, subpart M); Cellular Radiotelephone Service (part 22, subpart H); Citizens Broadband Radio Service (part 96, subpart C, of this chapter); Dedicated Short Range Communications Service, excluding public safety licenses (part 90, subpart M); Educational Broadband Service (part 27, subpart M); H Block Service (part 27, subpart K); Local Multipoint Distribution Service (part 101, subpart L); Multichannel Video Distribution and Data Service (part 101, subpart P); Multilateration Location and Monitoring Service (part 90, subpart M); Multiple Address Systems (EAs) (part 101, subpart O); Narrowband Personal Communications Service (part 24, subpart D); Paging and Radiotelephone Service (part 22, subpart E; part 90, subpart P); VHF Public Coast Stations,

including Automated Maritime Telecommunications Systems (part 80, subpart J, of this chapter); Upper Microwave Flexible Use Service (part 30 of this chapter); and Wireless Communications Service (part 27, subpart D).

* * * * *

■ 3. Amend § 1.9020 by revising paragraph (d)(2)(i) to read as follows:

§ 1.9020 Spectrum manager leasing arrangements.

* * * * *

(d) * * *

(2) * * *

(i) The spectrum lessee must meet the same eligibility and qualification requirements that are applicable to the licensee under its license authorization, with the following exceptions. A spectrum lessee entering into a spectrum leasing arrangement involving a licensee in the Public Safety Radio Services (see part 90, subpart B and § 90.311(a)(1)(i) of this chapter) is not required to comply with the eligibility requirements pertaining to such a licensee so long as the spectrum lessee is an entity providing communications in support of public safety operations (see § 90.523(b) of this chapter). A spectrum lessee entering into a spectrum leasing arrangement involving a licensee in the Mobile Satellite Service with ATC authority (see part 25 of this chapter) is not required to comply with the eligibility requirements pertaining to such a licensee so long as the spectrum lessee meets the other eligibility and qualification requirements of paragraphs (d)(2)(ii) and (iv) of this section.

* * * * *

■ 4. Amend § 1.9030 by revising paragraph (d)(2)(i) to read as follows:

§ 1.9030 Long-term *de facto* transfer leasing arrangements.

* * * * *

(d) * * *

(2) * * *

(i) The spectrum lessee must meet the same eligibility and qualification requirements that are applicable to the licensee under its license authorization. A spectrum lessee entering into a spectrum leasing arrangement involving a licensee in the Public Safety Radio Services (see part 90, subpart B and § 90.311(a)(1)(i) of this chapter) is not required to comply with the eligibility requirements pertaining to such a licensee so long as the spectrum lessee is an entity providing communications in support of public safety operations (see § 90.523(b) of this chapter).

* * * * *

§ 1.9047 [Removed and Reserved]

■ 5. Remove and reserve § 1.9047.

PART 27—MISCELLANEOUS WIRELESS COMMUNICATIONS SERVICES

■ 6. The authority citation for part 27 continues to read as follows:

Authority: 47 U.S.C. 154, 301, 302a, 303, 307, 309, 332, 336, 337, 1403, 1404, 1451, and 1452, unless otherwise noted.

■ 7. Amend § 27.4 by removing the definition for ''Commercial EBS licensee'' and revising the definition of ''Educational Broadband Service (EBS)'' to read as follows:

§ 27.4 Terms and definitions.

* * * * *

Educational Broadband Service (EBS). A radiocommunication service licensed under this part for the frequency bands specified in § 27.5(i).

* * * * *

§ 27.5 [Amended]

■ 8. Amend § 27.5 by removing and reserving paragraph (i)(3).

■ 9. Amend § 27.14 by:

■ a. Effective April 27, 2020, revising paragraphs (o) introductory text, (o)(2) introductory text, (o)(2)(iii), and (o)(3); and

■ b. Effective November 25, 2019, adding paragraphs (u) and (v).

The revisions and additions read as follows:

§ 27.14 Construction requirements.

* * * * *

(o) With respect to initial BRS licenses issued on or after November 6, 2009, the licensee must make a showing of substantial service within four years from the date of issue of the license. With respect to EBS licenses issued after October 25, 2019, the licensee must comply with paragraph (u) of this section. ''Substantial service'' is defined as service which is sound, favorable, and substantially above a level of mediocre service which just might minimally warrant renewal. Substantial service for BRS and EBS licensees is satisfied if a licensee meets the requirements of paragraph (o)(1), (2), or (3) of this section. If a licensee has not met the requirements of paragraph (o)(1), (2), or (3) of this section, then demonstration of substantial service shall proceed on a case-by-case basis. Except as provided in paragraphs (o)(4) and (5) of this section, all substantial service determinations will be made on a license-by-license basis. Failure by any licensee to demonstrate substantial service will result in forfeiture of the license and the licensee will be ineligible to regain it.

* * * * *

(2) An EBS license initially issued prior to October 25, 2019 has provided ''substantial service'' when:

* * * * *

(iii) The level of service provided by the EBS licensee meets or exceeds the minimum usage requirements specified in § 27.1214 contained in the edition of 47 CFR parts 20 through 39, revised as of October 1, 2017.

(3) An EBS or BRS licensee may be deemed to provide substantial service through a leasing arrangement if the lessee is providing substantial service under paragraph (o)(1) of this section.

* * * * *

(u) This section enumerates performance requirements for EBS licenses initially issued after October 25, 2019. Licensees shall demonstrate compliance with performance requirements by filing a construction notification with the Commission, within 15 days of the expiration of the applicable benchmark, in accordance with the provisions set forth in § 1.946(d) of this chapter.

(1) All EBS licenses initially issued after October 25, 2019, must demonstrate compliance with the performance requirements described in this paragraph (u). All equipment used to demonstrate compliance must be in use and actually providing service, either for internal use or to unaffiliated customers, as of the interim deadline or final deadline, whichever is applicable.

(2) Except for licensees with licenses applied for in the Tribal Priority Window, licensees providing mobile or point-to-multipoint service must demonstrate reliable signal coverage of 50% of the population of the geographic service area within four years of initial license grant, and 80% of the population of the geographic service area within eight years of initial license grant.

(3) Except for licensees with licenses applied for in the Tribal Priority Window, licensees providing fixed point-to-point service must demonstrate operation of one link for each 50,000 persons in the geographic service area within four years of initial license grant, and one link for each 25,000 persons in the geographic service area within eight years of initial license grant.

(4) Licensees with licenses applied for in the Tribal Priority Window must make an interim showing under paragraph (o)(2) or (3) of this section within two years of initial license grant. Licensees with licenses applied for in the Tribal Priority Window must make

a final showing under paragraph (o)(2) or (3) of this section within five years of initial license grant.

(5) If an EBS licensee (other than the licensee of a license issued pursuant to the Tribal Priority Window) fails to meet interim performance requirements described in paragraph (o)(2) or (3) of this section, the deadline for that authorization to meet its final performance requirement will be advanced by two years. If an EBS licensee of a license issued pursuant to the Tribal Priority Window fails to meet interim performance requirements described in paragraph (o)(2) or (3) of this section, the deadline for that authorization to meet its final performance requirement will be advanced by one year. If an EBS licensee fails to meet its final performance requirement, its license shall automatically terminate without specific Commission action.

(v) Paragraph (u) of this section contains new or modified information-collection and recordkeeping requirements. Compliance with these information-collection and recordkeeping requirements will not be required until after approval by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing that compliance date and revising this paragraph (v) accordingly.

§ 27.1201 [Removed and Reserved]

■ 10. Remove and reserve § 27.1201.

§ 27.1203 [Removed and Reserved]

■ 11. Remove and reserve § 27.1203.

■ 12. Effective November 25, 2019, add § 27.1204 to read as follows:

§ 27.1204 EBS Tribal priority filing window.

(a) The Commission will specify by public notice a window filing period for applications for new EBS stations on rural Tribal Lands. EBS applications for new facilities will be accepted only during this window. Applications submitted prior to the window opening date identified in the public notice will be returned as premature. Applications submitted after the deadline will be dismissed with prejudice as untimely.

(b) Applicants in the Tribal priority filing window must demonstrate that they are eligible to file in that window. To be considered eligible for the Tribal priority window, an applicant must be:

(1) A federally recognized American Indian Tribe or Alaska Native Village; or an entity that is owned and controlled by a federally-recognized Tribe or a consortium of federally-recognized Tribes;

(2) Requesting a license on Tribal Land, which is defined to be any federally recognized Indian Tribe's reservation, pueblo or colony, including former reservations in Oklahoma, Alaska Native regions established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) and Indian Allotments, see § 54.400(e) of this chapter, as well as Hawaiian Home Lands—areas held in trust for native Hawaiians by the State of Hawaii, pursuant to the Hawaiian Homes Commission Act, 1920, July 9, 1921, 42 Stat 108, *et seq.,* as amended; and any lands designated prior to July 10, 2019, as Tribal Lands pursuant to the designation process contained in § 54.412 of this chapter;

(3) Requesting a GSA in a rural area, which is defined to be lands that are not part of an urbanized area or urban cluster area with a population equal to or greater than 50,000; and

(4) Have a local presence on the Tribal Land for which they are applying.

(c) Following the close of the Tribal priority window, the Commission will issue a public notice of acceptance for filing of applications submitted pursuant to paragraph (b) of this section that meet technical and legal requirements and that are not in conflict with any other application filed during the window. Petitions to deny such applications may be filed within 30 days of such public notice. A copy of any petition to deny must be served on the applicant.

(d) If applications are filed in the Tribal priority window that are mutually exclusive, the Commission will use competitive bidding to resolve the mutual exclusivity. Two or more pending applications are mutually exclusive if the grant of one application would effectively preclude the grant of one or more of the others under Commission rules in this chapter.

(e) For non-mutually exclusive applications, the applications will be processed in accordance with procedures to be specified by the Wireless Telecommunications Bureau.

(f) This section contains new or modified information-collection and recordkeeping requirements. Compliance with these information-collection and recordkeeping requirements will not be required until after approval by the Office of Management and Budget. The Commission will publish a document in the **Federal Register** announcing that compliance date and revising this paragraph (f) accordingly.

■ 13. Add § 27.1205 to read as follows:

§ 27.1205 EBS renewal standard.

In applying the renewal standard contained in § 1.949 of this chapter to EBS, for licenses initially issued after October 25, 2019, the applicable safe harbors are the buildout standards contained in § 27.14(u). For licenses initially issued before October 25, 2019, the applicable safe harbors are the buildout standards contained in § 27.14(o); provided, however, that the educational use safe harbor contained in § 27.14(o)(2) may only be used by a licensee that meets the eligibility requirements to hold an EBS license pursuant to the provisions of § 27.1201(a) contained in the edition of 47 CFR parts 20 through 39, revised as of October 1, 2017.

■ 14. Revise § 27.1206 to read as follows:

§ 27.1206 Geographic service area.

(a) BRS:

(1) For BRS incumbent licenses granted before September 15, 1995, the geographic service area (GSA) is the area that is bounded by a circle having a 35 mile radius and centered at the station's reference coordinates, which was the previous PSA entitled to incumbent licensees prior to January 10, 2005, and is bounded by the chord(s) drawn between intersection points of the licensee's previous 35 mile PSA and those of respective adjacent market, co-channel licensees;

(2) For BRS BTA authorization holders, the GSA for a channel is the BTA, subject to the exclusion of overlapping, co-channel incumbent GSAs created on January 10, 2005.

(3) If an incumbent BRS license is cancelled or is forfeited, the GSA area of the incumbent station shall dissolve and the right to operate in that area automatically reverts to the GSA licensee that held the corresponding BTA.

(b) EBS:

(1) *Existing EBS licensees.* (i) The GSA of EBS licenses on the E and F channel groups is defined in § 27.1216. EBS licensees on the E and F channel groups are prohibited from expanding their GSAs.

(ii) For incumbent EBS licenses not in the E and F channel groups in effect as of October 25, 2019, the geographic service area (GSA) is the area that is bounded by a circle having a 35 mile radius and centered at the station's reference coordinates, which was the previous PSA entitled to incumbent licensees prior to January 10, 2005, and is bounded by the chord(s) drawn between intersection points of the licensee's previous 35 mile PSA and

those of respective adjacent market, co-channel licensees.

(2) *New initial EBS licenses.* (i) For EBS licenses issued in the Tribal Priority Window, the GSA consists of the rural Tribal Land (as defined in § 27.1204(b)(3)) specified in the application.

(ii) For all other new initial licenses issued after April 27, 2020, the GSA is the county for which the license is issued, subject to the exclusion of overlapping, co-channel incumbent GSAs.

■ 15. Revise § 27.1207 to read as follows:

§ 27.1207 Service areas and authorizations.

(a) Initial authorizations for BRS granted after January 1, 2008, shall be blanket licenses for all BRS frequencies identified in § 27.5(i)(2). Except for incumbent BRS licenses, BRS service areas are the 1992 version of Basic Trading Areas (BTAs) defined by Rand McNally, or additional service areas similar to BTAs adopted by the Commission. The market area for each license will be listed on the license authorization. The following are additional BRS service areas in places where Rand McNally has not defined BTAs: American Samoa; Guam; Gulf of Mexico Zone A; Gulf of Mexico Zone B; Gulf of Mexico Zone C; Northern Mariana Islands; Mayaguez/Aguadilla-Ponce, Puerto Rico; San Juan, Puerto Rico; and the United States Virgin Islands. The boundaries of Gulf of Mexico Zone A are from an area twelve nautical miles from the shoreline at mean high tide on the north and east, to the limit of the Outer Continental Shelf to the south, and to longitude 91°00′ to the west. The boundaries of Gulf of Mexico Zone B are from an area twelve nautical miles from the shoreline at mean high tide on the north, to the limit of the Outer Continental Shelf to the south, to longitude 91°00′ to the east, and to longitude 94°00′ to the west. The boundaries of Gulf of Mexico Zone C are from an area twelve nautical miles from the shoreline at mean high tide on the north and west, to longitude 94°00′ to the east, and to a line 281 kilometers from the reference point at Linares, N.L., Mexico on the southwest. The Mayaguez/Aguadilla-Ponce, PR, service area consists of the following municipios: Adjuntas, Aguada, Aguadilla, Anasco, Arroyo, Cabo Rojo, Coamo, Guanica, Guayama, Guayanilla, Hormigueros, Isabela, Jayuya, Juana Diaz, Lajas, Las Marias, Maricao, Maunabo, Mayaguez, Moca, Patillas, Penuelas, Ponce, Quebradillas, Rincón, Sabana Grande, Salinas, San German, Santa Isabel, Villalba and Yauco. The San Juan service area consists of all other municipios in Puerto Rico.

(b) For EBS initial licenses issued after October 25, 2019, except for licenses issued in the Tribal Priority Window, the GSA is the county for which the license is issued, subject to the exclusion of overlapping, co-channel incumbent GSAs. For purposes of this subpart, counties are defined using the United States Census Bureau's data reflecting county legal boundaries and names valid through January 1, 2017. Except for licenses issued in the Tribal Priority Window, there shall be three initial authorizations issued in each county: One authorization for channels A1, A2, A3, B1, B2, B3, C1, C2, and C3; the second authorization for channels D1, D2, D3, JA1, JA2, JA3, JB1, JB2, JB3, JC1, JC2, JC3, JD1, JD2, JD3, A4, B4, C4, D4, and G4; the third authorization for channels G1, G2, G3, KG1, KG2, and KG3.

■ 16. Revise § 27.1208 to read as follows:

§ 27.1208 Geographic area licensing.

(a) All BRS and EBS licenses are geographic area licenses. Blanket licenses cover all mobile and response stations. Pursuant to that geographic area license, incumbent licensees may modify their systems provided the modified system complies with the applicable rules in this chapter. The blanket license covers all fixed stations anywhere within the authorized service area, except a station must be individually licensed if:

(1) International agreements require coordination;

(2) Submission of an Environmental Assessment is required under § 1.1307 of this chapter; and

(3) The station would affect the radio quiet zones under § 1.924 of this chapter.

(b) Any antenna structure that requires notification to the Federal Aviation Administration (FAA) must be registered with the Commission prior to construction under § 17.4 of this chapter.

■ 17. Revise § 27.1209 to read as follows:

§ 27.1209 Reversion and overlay rights.

(a) The frequencies associated with BRS incumbent authorizations that have cancelled automatically or otherwise recovered by the Commission automatically revert to the applicable BRS BTA licensee.

(b) The frequencies associated with EBS incumbent authorizations with a geographic service area that have cancelled automatically or otherwise recovered by the Commission automatically revert to a co-channel EBS county-based licensee, except that if the area in question is Tribal Land as defined in § 27.1204(b)(3) and is contiguous to the GSA of a co-channel authorization issued in the Tribal Priority Window, the area consisting of Tribal Land reverts to the co-channel license issued in the Tribal Priority Window.

(c) The frequencies associated with EBS authorizations issued in the Tribal Priority Window with a geographic service area that have cancelled automatically or otherwise recovered by the Commission automatically revert to a co-channel EBS county-based authorization.

■ 18. Revise § 27.1214 to read as follows:

§ 27.1214 EBS grandfathered leases.

All leases of current EBS spectrum entered into prior to January 10, 2005 and in compliance with leasing rules contained in 47 CFR part 74, revised as of October 1, 2004, may continue in force and effect, notwithstanding any inconsistency between such leases and the rules applicable to spectrum leasing arrangements set forth in this chapter. Such leases entered into pursuant to the rules formerly contained in 47 CFR part 74 may be renewed and assigned in accordance with the terms of such lease. All spectrum leasing arrangements leases entered into after January 10, 2005, under the rules set forth in part 1 of this chapter and this part, must comply with the rules in those parts.

■ 19. Revise § 27.1217 to read as follows:

§ 27.1217 Competitive bidding procedures for the Broadband Radio Service and the Educational Broadband Service.

Mutually exclusive initial applications for BRS and EBS licenses are subject to competitive bidding. For BRS auctions, the designated entity provisions of § 27.1218 apply. For EBS auctions, the designated entity provisions of § 27.1219 apply. The general competitive bidding procedures set forth in part 1, subpart Q, of this chapter apply unless otherwise provided in this subpart.

■ 20. Amend § 27.1218 by revising the section heading to read as follows:

§ 27.1218 Broadband Radio Service designated entity provisions.

* * * * *

■ 21. Add § 27.1219 before the undesignated center heading ''Technical Standards'' to read as follows:

§ 27.1219 Educational Broadband Service designated entity provisions.

(a) *Eligibility for small business provisions.* (1) A small business is an entity that, together with its affiliates, its controlling interests and the affiliates of its controlling interests, have average gross revenues that are not more than $55 million for the preceding five (5) years.

(2) A very small business is an entity that, together with its affiliates, its controlling interests and the affiliates of its controlling interests, has average gross revenues that are not more than $20 million for the preceding five (5) years.

(b) *Bidding credits.* A winning bidder that qualifies as a small business, as defined in this section, or a consortium of small businesses may use a bidding credit of 15 percent, as specified in § 1.2110(f)(2)(i)(C) of this chapter. A winning bidder that qualifies as a very small business, as defined in this section, or a consortium of very small businesses may use a bidding credit of 25 percent, as specified in § 1.2110(f)(2)(i)(B) of this chapter.

(c) *Rural service provider credit.* A rural service provider, as defined in § 1.2110(f)(4) of this chapter, who has not claimed a small business bidding credit may use a bidding credit of 15 percent bidding credit, as specified in § 1.2110(f)(4)(i) of this chapter.

§§ 27.1230 through 27.1239 [Removed]

■ 22. Remove the undesignated center heading ''Policies Governing the Transition of the 2500–2690 MHz Band for BRS and EBS'' and §§ 27.1230 through 27.1239.

[FR Doc. 2019–22511 Filed 10–24–19; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 141107936–5399–02]

RIN 0648–XS014

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; 2019 Commercial Accountability Measure and Closure for South Atlantic Gray Triggerfish; July Through December Season

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements accountability measures for commercial gray triggerfish in the exclusive economic zone (EEZ) of the South Atlantic. NMFS projects commercial landings for gray triggerfish will reach the commercial annual catch limit (ACL)(commercial quota) for the July through December season by October 27, 2019. Therefore, NMFS is closing the commercial sector for gray triggerfish in the South Atlantic EEZ on October 27, 2019. This closure is necessary to protect the gray triggerfish resource.

DATES: This rule is effective 12:01 a.m., local time, October 27, 2019, through December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes gray triggerfish and is managed under the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The FMP was prepared by the South Atlantic Fishery Management Council and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The commercial ACL (commercial quota) for gray triggerfish in the South Atlantic is divided into two 6-month fishing seasons. The total commercial ACL of 312,324 lb (141,668 kg), round weight, is allocated 50 percent to each commercial fishing season, or 156,162 lb (70,834 kg), round weight, each, for January through June, and July through December, as specified in 50 CFR 622.190(a)(8)(i) and (ii).

Under 50 CFR 622.193(q)(1)(i), NMFS is required to close the commercial sector for gray triggerfish when the commercial quota specified in 50 CFR 622.190(a)(8)(ii) is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined that the commercial quota for South Atlantic gray triggerfish for the July through December fishing season will be reached by October 27, 2019. Accordingly, the commercial sector for South Atlantic gray triggerfish is closed effective at 12:01 a.m., local time, October 27, 2019, until the start of the January through June fishing season on January 1, 2020.

The operator of a vessel with a valid Federal commercial vessel permit for South Atlantic snapper-grouper having gray triggerfish on board must have landed and bartered, traded, or sold such gray triggerfish prior to 12:01 a.m., local time, October 27, 2019. During the closure, the recreational bag limit specified in 50 CFR 622.187(b)(8), and the possession limits specified in 50 CFR 622.187(c), apply to all harvest or possession of gray triggerfish in or from the South Atlantic EEZ. Also, during the closure, the sale or purchase of gray triggerfish taken from the South Atlantic EEZ is prohibited. The prohibition on the sale or purchase does not apply to gray triggerfish that were harvested, landed ashore, and sold prior to 12:01 a.m., local time, October 27, 2019, and were held in cold storage by a dealer or processor.

For a person on board a vessel for which a valid Federal commercial or charter vessel/headboat permit for the South Atlantic snapper-grouper fishery has been issued, the bag and possession limits and sale and purchase prohibitions for gray triggerfish apply regardless of whether the fish are harvested in state or Federal waters, as specified in 50 CFR 622.190(c)(1)(ii).

Classification

The Regional Administrator, NMFS Southeast Region, has determined this temporary rule is necessary for the conservation and management of gray triggerfish and the South Atlantic snapper-grouper fishery and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.193(q)(1)(i) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The Assistant Administrator for NOAA Fisheries (AA), finds that the need to immediately implement this action to close the commercial sector for gray triggerfish constitutes good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth in 5 U.S.C. 553(b)(B), as such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the final rules implementing the split commercial season for gray triggerfish and the commercial closure provisions have already been subject to notice and comment, and all that remains is to notify the public of the closure. Such procedures are contrary to the public interest because of the need to

immediately implement this action to protect gray triggerfish since the capacity of the fishing fleet allows for rapid harvest of the commercial quota. Prior notice and opportunity for public comment would require time and would potentially result in a harvest well in excess of the established commercial quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: October 22, 2019.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2019–23352 Filed 10–22–19; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 84, No. 207
Friday, October 25, 2019

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 925 and 944

[Doc. No. AMS–SC–16–0009; SC16–925–2]

Grapes Grown in Designated Area of Southeastern California and Imported Table Grapes; Removing Varietal Exemptions; Withdrawal

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Withdrawal of proposed rule.

SUMMARY: The U.S. Department of Agriculture withdraws a proposed rule recommended by the California Desert Grape Administrative Committee (Committee) to remove varietal exemptions from the California table grape marketing order and the table grape import regulation as well as to remove administrative exemptions previously granted for certain varieties of imported grapes. After reviewing and considering the comments received, the proposed rule is being withdrawn.

DATES: As of October 25, 2019, the proposed rule published on June 23, 2017, at 82 FR 28589, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Maria Stobbe, Marketing Specialist, or Terry Vawter, Senior Marketing Specialist, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Maria.Stobbe@ams.usda.gov* or *Terry.Vawter@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This withdrawal is issued under Marketing Order No. 925, as amended (7 CFR part 925), regulating the handling of grapes grown in a designated area of southeastern California. Part 925 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred as the ''Act.'' The Committee locally administers the Order and is comprised of producers of California table grapes grown in a designated area of southeastern California, and a public member.

This withdrawal is also issued under section 8e of the Act, which provides that whenever certain specific commodities, including table grapes, are regulated under a Federal marketing order, imports of those commodities into the United States are prohibited unless they meet the same or comparable quality, grade, size, and maturity requirements as those in effect for the domestically produced commodity.

This action withdraws a proposed rule published in the **Federal Register** on June 23, 2017, (82 FR 28589) to remove varietal exemptions from the Order and import regulation as well as to remove administrative exemptions from the import regulation. Specifically, the proposed rule would have removed existing varietal exemptions (Emperor, Calmeria, Almeria, and Ribier) from the Order. As a result, all table grapes, regardless of variety, grown in the production area during the regulatory period (April 10 through July 10 each year) would have been subject to grade, size, quality, maturity, pack, and container requirements of the Order and would have been subject to inspection and certification requirements.

Additionally, the proposed rule would have removed the same varietal exemptions from the import regulation. Accordingly, all table grapes imported into the United States during the regulatory period would have been subject to grade, size, quality, and maturity regulations specified in the import regulation and would have been subject to inspection and certification requirements.

In conjunction with these changes, the proposed rule would have removed administrative exemptions from the import regulation for sixteen imported varieties (Italia Pirovano [Blanca Italia], Christmas Rose, Muscatel, Barlinka, Dauphine, Kyoho, Waltham Cross, Alphonse Lavallee, Bien Donne, Bonnoir [Bonheur], La Rochelle, Queen, Rouge, Sonita, Tokay, and Red Globe).

During the proposed rule's 60-day comment period, fifteen comments were received. All the comments may be viewed on the internet at *http://www.regulations.gov.* Of the fifteen comments received, one was in support, thirteen were opposed, and one did not pertain to the issue raised in the proposed rule. The supportive comment was from a California table grape industry association and was in favor of the proposed changes. Each of the thirteen opposing commenters represented an entity involved in the importation or marketing of imported table grapes: Six were from distributors of imported grapes based in Delaware, Pennsylvania, New Jersey, and California; two represented shipping ports; three represented trade associations; one was from an exporters' association; and one was from a foreign embassy.

The opposing comments noted that the changes would result in job losses as well as a substantive increase in burden and costs to shippers and exporters in handling and storage costs, without adding quality benefits. The commenters stated that this could lead to reduced efficiency and vitality of export operations. Commenters also stated inspection delays and associated costs are not warranted because imported grapes do not compete on a seeded vs seedless basis. Another commenter noted that the changes would represent a major barrier to trade by eliminating exemptions, thereby restricting the flow of table grapes to market, causing economic harm to the shipper and possibly the consumer of table grapes.

Some commenters stated that the proposed rule did not contain quantifiable data that demonstrated support for the removal of all grape varietal exemptions from the Order and that no evidence supported eliminating previously exempted varieties shipped and sold prior to the first availability of the same comparable domestic varieties. In addition, they stated that imported grapes have not been shown to impact prices on any of the domestically produced exempted varieties.

Commenters also contended that the proposed changes are not supported by law or data and that it is not appropriate to deviate from the long-standing agency determination to exempt varieties not domestically produced.

After reviewing and considering the comments received, the Agricultural Marketing Service (AMS) has determined that the proposed rule to remove varietal exemptions from the Order and the table grape import

regulation should not be finalized. AMS intends to conduct outreach with the California table grape industry stakeholders and consider whether changes will be proposed in the future. Accordingly, the proposed rule to remove varietal exemptions from the Order and import regulation published in the **Federal Register** on June 23, 2017, (82 FR 28589) is hereby withdrawn.

List of Subjects in 7 CFR Part 925

Grapes, Marketing agreements, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 601–674.

List of Subjects in 7 CFR Part 944

Avocados, Food grades and standards, Grapefruit, Grapes, Imports, Kiwifruit, Limes, Olives, Oranges.

Authority: 7 U.S.C. 601–674.

Dated: October 21, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–23236 Filed 10–24–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Parts 244 and 259

[Docket No. DOT–OST–2019–0144]

RIN 2105–AE47

Tarmac Delay Rule

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This rulemaking would modify U.S. and foreign air carrier obligations with respect to tarmac delays and conform carrier obligations with respect to departure delays with the changes made to the FAA Extension, Safety, and Security Act of 2016. This rulemaking would also make changes to the notification requirements regarding the status of the tarmac delay and the opportunity to deplane as well as carrier tarmac delay reporting and record retention requirements.

DATES: Comments should be filed by December 24, 2019. Late-filed comments will be considered to the extent practicable.

ADDRESSES: You may file comments identified by the docket number DOT–OST–2019–9144 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE, between 9:00 a.m. and 5:00 p.m. ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

Instructions: You must include the agency name and docket number DOT–OST–2019–0144 or the Regulatory Identification Number (RIN) for the rulemaking at the beginning of your comment. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.) You may review DOT's complete Privacy Act statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://DocketsInfo.dot.gov.*

Docket: For access to the docket to read background documents and comments received, go to *http://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Ryan Patanaphan, Senior Trial Attorney or Blane A. Workie, Assistant General Counsel, Office of Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, 202–366–9342, 202–366–7152 (fax), *ryan.patanaphan@dot.gov* or *blane.workie@dot.gov* (email).

SUPPLEMENTARY INFORMATION:

Current Tarmac Delay Requirements

On April 25, 2011, the Department published the ''Enhancing Airline Passenger Protections'' rule to improve the air travel environment for passengers.[1] Under this rule, carriers are required to adopt and adhere to tarmac delay contingency plans. DOT's regulations require that these plans contain assurances that covered carriers will not allow aircraft to remain on the tarmac for more than three hours for domestic flights and four hours for international flights without providing passengers the option to deplane subject to exceptions for safety, security, and Air Traffic Control related reasons. Carriers' plans must also contain assurances such as assurances that carriers will provide adequate food and drinking water within two hours of the aircraft being delayed on the tarmac, provide notifications regarding the status of the delay and the opportunity to deplane if the opportunity to deplane exists, maintain operable lavatories and, if necessary, provide medical attention.

Need for a Rulemaking

Section 2308 of the FAA Extension, Safety, and Security Act of 2016, Public Law 114–190 (FAA Extension Act) requires the Department to issue regulations and take other actions necessary to carry out the amendments made by Section 2308. These amendments include new language requiring air carriers to begin to return an aircraft to a suitable disembarkation point no later than 3 or 4 hours after the main aircraft door is closed for departure. In response, the Department's Office of Aviation Enforcement and Proceedings (Enforcement Office) issued an ''Enforcement Policy on Extended Tarmac Delays'' (Enforcement Policy)[2] on November 22, 2016. The Enforcement Policy states that, as a matter of prosecutorial discretion, the Department will not take enforcement action against U.S. and foreign air carriers with respect to departure delays if U.S. and foreign air carriers begin to return the aircraft to a gate or another suitable disembarkation point no later than three hours for domestic flights and no later than four hours for international flights after the main aircraft door has closed in preparation for departure. The Enforcement Policy further provides that the process of beginning to return to the gate or a suitable disembarkation point varies based on whether the aircraft is in a carrier-controlled part of the airport or a non-carrier-controlled part of the airport. The Enforcement Policy is intended to be a temporary fix until the Department issues a final rule that specifically addresses lengthy tarmac delays pursuant to the FAA Extension Act.

In October 2017, the Department published a Notification of Regulatory Review (82 FR 4570, October 2, 2017), seeking public input on existing rules and other agency actions that are good candidates for repeal, replacement,

[1] Enhancing Airline Passenger Protections Rule, 76 FR 23110, Apr. 25, 2011.

[2] *https://www.transportation.gov/airconsumer/enforcement-policy-extended-tarmac-delays.*

suspension, or modification.[3] DOT received comments from various regulated entities regarding the Department's tarmac delay rule.[4] Further, on January 30, 2019, the Department issued a notice inviting the public to identify and provide input on existing guidance documents that are good candidates for repeal, replacement, or modification.[5] American Airlines and jointly A4A and IATA filed comments related to the 2016 Enforcement Policy.

The Department has reviewed these comments and is proposing certain changes to the tarmac delay rule, primarily a new exception for departure delays to conform the regulations to the FAA Extension Act, provide greater flexibility to airlines, and alleviate concerns about the existing rule's potential effects on cancellations. DOT is also proposing several changes to reporting requirements and other carrier obligations with respect to tarmac delays. The proposals are described in more detail below. The Department plans to consider the comments received on the tarmac delay rule that are not addressed in this proposal at a later time.

Notice of Proposed Rulemaking

1. Departure Delay Exception

On July 15, 2016, the FAA Extension Act was signed. Section 2308 of the FAA Extension Act amends 49 U.S.C. 42301 by changing the standard for when tarmac delay violations occur with respect to departing flights. The FAA Extension Act requires the Department to issue regulations and take other actions necessary to carry out section 2308. Under section 2308 of the FAA Extension Act, a tarmac delay occurs when passengers are on board an aircraft on the tarmac (A) awaiting takeoff after the main aircraft door is closed in preparation for departure, or (B) awaiting deplaning after the aircraft has landed. Under that Act, an excessive tarmac delay is a tarmac delay that is more than three hours long for domestic flights or more than four hours long for international flights. Previously, an excessive tarmac delay was defined in 49 U.S.C. 42301 as a tarmac delay that lasts for a length of time as determined by the Department.

In its amended form, 49 U.S.C. 42301 provides that a tarmac delay ends for an arriving and departing flight when a passenger has the option to deplane an aircraft and return to the airport terminal; however, for a departing flight, under amended section 42301, it is not a violation of the assurance to permit an aircraft to remain on the tarmac for more than three hours for domestic flights and more than four hours for international flights if the air carrier begins to return the aircraft to a suitable disembarkation point to deplane passengers by those times. Unlike the amended statute, DOT's current regulation prohibits a carrier from allowing an aircraft to remain on the tarmac for more than three hours for domestic flights and four hours for international flights without providing passengers the opportunity to deplane and applies this standard to both departing and arriving flights without consideration of the time the carrier begins to return the aircraft to a suitable disembarkation point for departing flights.

In the Enforcement Policy, the Department has stated that, if the aircraft is in an area of the airport property that is not under the carrier's control, the aircraft has begun the process of returning to a suitable disembarkation point when permission is granted by the Federal Aviation Administration (FAA) control tower, airport authority, or other relevant authority directing the aircraft's operations while it is on the tarmac. However, if the aircraft is in an area of the airport property that is under the carrier's control, an aircraft has begun to return to a suitable disembarkation point when the pilot begins maneuvering the aircraft to the disembarkation point.

DOT is proposing to amend its tarmac delay regulation to reflect its Enforcement Policy, with slight modifications. To determine when the carrier begins to return to a suitable disembarkation point, we are proposing that if the aircraft is in an area that is not under the carrier's control, then the aircraft has begun to return to a suitable disembarkation point when a request is made to the Federal Aviation Administration control tower, airport authority, or other relevant authority directing the aircraft's operations, rather than when permission is granted as set forth in the Enforcement Policy. This revision would ensure that carriers are not held responsible for delays attributed to third parties and beyond the carriers' control. However, similar to the Enforcement Policy, under this proposed rule, if the aircraft is in an area of the airport property that is under the carrier's control, an aircraft would be considered to have begun to return to a suitable disembarkation point when the pilot begins maneuvering the aircraft to the disembarkation point. The Department seeks comment on this proposed standard and whether there are other appropriate standards the Department should consider.

In addition, this rulemaking takes into account circumstances when a carrier has closed the main aircraft door for departure but the aircraft has not left the gate. Under the Enforcement Policy, the tarmac delay clock for departing flights begins when the main aircraft door has closed, even if the aircraft remains at the gate and the carrier asserts that an opportunity to deplane still exists. This rulemaking proposes that a tarmac delay on a departing flight begins when the main aircraft door is closed, which generally means that passengers on board the flight no longer have the opportunity to deplane. If a carrier can show that passengers on board the aircraft have the opportunity to deplane from an aircraft, even while the aircraft doors are closed, then, under the proposal, the tarmac delay clock has not started and will not start until passengers no longer have the opportunity to deplane. Absent a showing that passengers have the opportunity to deplane while the aircraft is at the gate with the doors closed, there would be a presumption that passengers do not have an opportunity to deplane. This approach allows carriers some flexibility in determining when a tarmac delay begins, while adhering to the standard prescribed by the statute. DOT seeks comment on this approach to determining when a tarmac delay begins during departing flights.

DOT believes that adopting the departure delay exception as described in the Enforcement Policy—that a departing flight is not considered to be in violation of the assurance not to permit an aircraft to remain on the tarmac for more than 3 hours for domestic flights and more than 4 hours for international flights so long as the air carrier begins to return the aircraft to a suitable disembarkation point—would provide covered carriers some relief in situations when they may be unable to reduce the length of a tarmac delay for circumstances beyond their control. While in most cases a carrier would violate the current tarmac delay regulation if the carrier has not provided passengers the opportunity to deplane

[3] *https://www.regulations.gov/document?D=DOT-OST-2017-0069-0001.*

[4] The Department received comments from Airlines For America (A4A), United Airlines, International Air Transport Association (IATA), Kuwait Airways, National Air Carrier Association (NACA), Etihad Airways, Association of Asian Pacific Airlines (AAPA), Lufthansa Group, Qantas, El Al, WestJet, Airlines Association of Southern Africa, and Air France/KLM related to the tarmac delay rule. In addition, the Department met with A4A and various U.S. airlines to hear their views of the tarmac delay rule.

[5] *https://www.regulations.gov/document?D=DOT-OST-2017-0069-2855.*

by either the three or four-hour mark, the proposed inclusion of the departure delay exception offers carriers more flexibility and reduces the number of tarmac delays that are subject to enforcement. This would reduce the burden of the tarmac delay regulation on carriers in situations that they may be unable to control, while still maintaining important consumer protections.

Also, the proposal specifies that the exception applies when carriers begin to return to a suitable disembarkation point *in order to deplane passengers.* If a flight begins to return to a suitable disembarkation point but does not provide passengers an opportunity to deplane, absent one of the safety, security, or air traffic control (ATC) exceptions provided in the regulation, the flight would not be considered to have begun to return to a suitable disembarkation point to provide passengers an opportunity to deplane, and the tarmac delay clock would continue to run. For example, an aircraft that begins the process to return to the gate or another suitable disembarkation point for a mechanical-related problem would have the tarmac delay time continue accruing for the flight if the purpose of the return was not to provide passengers an opportunity to deplane and passengers were not provided the option to deplane.

We note that even though the requirements in 49 U.S.C. 42301, which were amended by the FAA Extension Act, only apply to U.S. carriers, DOT chose to apply its Enforcement Policy to both U.S. and foreign air carriers, under DOT's authority to prohibit unfair and deceptive practices in 49 U.S.C. 41712. We are also proposing to apply the requirements in the proposed rule to both U.S. and foreign air carriers to streamline the tarmac delay requirements and decrease confusion in the airport environment. DOT seeks comment on this approach.

DOT is not proposing to change carrier obligations with respect to tarmac delays for arriving flights. Section 2308 of the FAA Extension Act states that the departure delay standard applies to departing flights, and, as such, DOT proposes to require carriers to modify their Contingency Plan for Lengthy Tarmac Delays to include specific assurances related to such flights.

With regard to diverting flights, this proposal would provide that diversions are treated as arriving flights up to the point that an opportunity to deplane is provided to passengers. Once an opportunity to deplane is provided, the diversion is treated as a departing flight and after that point, the departure delay exception applies if carriers begin to return to a suitable disembarkation point in order to deplane passengers. DOT seeks comment on this treatment of diverting flights.

2. Reporting Requirements

DOT proposes to revise the tarmac delay reporting requirements in 14 CFR part 244. Currently, reporting carriers [6] are required to file BTS Form 234 ''On-Time Flight Performance Report'' on a monthly basis for all scheduled passenger domestic flights that they market under their code to or from any U.S. large, medium, small, or non-hub airport. The report includes information on domestic scheduled passenger flights that experience tarmac delays at U.S. airports. Reporting carriers are also required to file BTS Form 244 ''Tarmac Delay Report'' on a monthly basis to report information on passenger flights that they operate that experience lengthy tarmac delays, including domestic scheduled passenger flights that experience lengthy tarmac delays at medium, small, or non-hub U.S. airports to the extent the carriers do not already report on-time performance data voluntarily for these airports under 14 CFR 234.7.[7] This has resulted in duplicative reporting.

Today, reporting carriers are required to submit tarmac delay information for scheduled domestic flights that they operate at medium, small, or non-hub U.S. airports both through Form 234 and Form 244. Also, tarmac delays on scheduled domestic flights marketed but not operated by a reporting carrier are being reported twice: The reporting carrier reports the flight using BTS Form 234, and the non-reporting carrier reports the same flight using BTS Form 244. This rulemaking would provide that tarmac delays on scheduled domestic passenger flights need no longer be reported by reporting carriers under 14 CFR part 244, provided that such flights are reported under 14 CFR part 234. Also, the proposed rule changes reporting requirements to relieve non-reporting carriers of the obligation of filing BTS Form 244 for scheduled domestic flights if such flights are already reported by the reporting carrier to the Department using BTS Form 234. This change would reduce the burden on non-reporting carriers that operate flights held out by reporting carriers. U.S. air carriers covered under 14 CFR part 234 would still be required to file BTS Form 244 for tarmac delays occurring on international and public charter flights, and on flights not otherwise reported under 14 CFR part 234 (*e.g.,* extra section flights). Non-reporting U.S. carriers that operate flights that are not held out by reporting carriers would still be required to file BTS Form 244 for tarmac delays on domestic and international flights. The Department requests comment on the above reporting changes, including whether and how reporting requirements in 14 CFR parts 234 and 244 can be further consolidated.

With respect to international flights, carriers are currently required to file a report under 14 CFR part 244 for tarmac delays of more than three hours. Under this proposed rule, the requirement to report would only be triggered if the tarmac delay rises to the level of an ''excessive tarmac delay,'' defined as a tarmac delay of more than three hours for a domestic flight and more than four hours for an international flight. This would reduce the number of instances in which a carrier is required to report to the Department a tarmac delay on an international flight. The Department solicits comment on this approach.

3. Record Retention

DOT proposes to eliminate the tarmac delay record retention requirement in 14 CFR 259.4(e) and replace it with a reporting requirement. The current rule requires that U.S. and foreign air carriers with a tarmac delay contingency plan retain for two years specific information related to a tarmac delay. The specific information includes, among other information, the length and cause of the delay and an explanation of the actions taken to minimize passenger hardship. Under 49 U.S.C. 42301(h), U.S. carriers are also required to submit a written description of each excessive tarmac delay, which may include the information required to be retained

[6] ''Reporting carrier'' for air transportation taking place on or after January 1, 2018, means an air carrier certificated under 49 U.S.C. 41102 that accounted for at least 0.5 percent of domestic scheduled-passenger revenues in the most recently reported 12-month period as defined by the Department's Office of Airline Information, and as reported to the Department pursuant to part 241 of this chapter. Reporting carriers will be identified periodically in accounting and reporting directives issued by the Office of Airline Information. 14 CFR 234.2.

[7] Reporting carriers are not required to file BTS Form 244 to report information on scheduled flights that experience lengthy tarmac delays at large hub U.S. airports because when DOT issued its rule for carriers to file BTS Form 244, that information was already required to be reported for domestic scheduled flights at large hub airports through BTS Form 234. Since then, the requirement for reporting carriers to provide on-time performance data using BTS Form 234 has been expanded to cover medium, small and non-hub airports. Also, the reporting of on-time performance data for scheduled domestic flights at medium, small, or non-hub U.S. airports on BTS Form 234 is mandatory and no longer voluntary for reporting carriers.

under 14 CFR 259.4(e). Because the Department receives a written description of lengthy tarmac delays from U.S. carriers as mandated by statute, maintaining the record retention requirement for U.S. carriers is duplicative and of limited or no public benefit. As such, the Department proposes to change the record retention requirement in 14 CFR 259.4(e) to a reporting requirement, thereby eliminating the requirement to retain certain information for two years.

The new reporting requirement would include the same information currently required to be retained under the current § 259.4(e), and would also satisfy U.S. carrier obligations under 49 U.S.C. 42301(h). To comply with the mandate in 49 U.S.C. 42301(h) for U.S. carriers to submit to the Department a written description of a flight that experiences an excessive tarmac delay and its resolution, U.S. carriers generally provide the Department with the same information that they are required to retain under § 259.4(e): The name of the operating carrier, the flight number, the origin and destination airports, the location of the delay, the length of the tarmac delay, and an explanation of the incident, including the cause of the delay and actions taken to minimize passenger hardship. This NPRM proposes that the same information be provided to the Department by U.S. and foreign air carriers under 14 CFR 259.4. Although 49 U.S.C. 42301(h) applies only to U.S. carriers, the Department is proposing to apply the same requirement to foreign air carriers pursuant to the Department's authority under 49 U.S.C. 41712. Accordingly, under the proposal, U.S. and foreign air carriers would file one written description of each excessive tarmac delay incident to the Department. As explained earlier, the airlines would no longer be required to retain for two years the records listed in 14 CFR 259.4(e). For both U.S. and foreign air carriers, the new reports would be due within 30 days of the date an excessive tarmac delay occurs, which is consistent with the time frame reports are due for U.S. carriers under 49 U.S.C. 42301(h). The Department requests comment on the above reporting and record retention changes, including the type of information to be required for reporting.

4. Other Exceptions to Tarmac Delay Requirements

Under the Department's existing tarmac delay rule, carriers must not allow an aircraft to remain on the tarmac for more than three hours for domestic flights and more than four hours for international flights before allowing passengers to deplane from an aircraft, except when the pilot-in-command determines that there is a safety-related or security-related reason why the aircraft cannot leave its position on the tarmac to deplane passengers, or when air traffic control advises that returning to a suitable disembarkation point to deplane passengers would significantly disrupt airport operations. Under 49 U.S.C. 42301, a passenger must have the option to deplane an aircraft and return to the airport terminal when there is a lengthy tarmac delay except when the pilot in command determines that permitting a passenger to deplane would jeopardize passenger safety or security, or when air traffic control advises that returning to a suitable disembarkation point to deplane passengers would significantly disrupt airport operations. Title 49 U.S.C. 42301 also references a suitable disembarkation point when discussing deplaning passengers following a lengthy tarmac delay.

This rulemaking proposes to amend the safety and security exceptions to the tarmac delay rule to codify the exceptions in 49 U.S.C. 42301. Under this proposal, a safety or security exception occurs when the pilot-in-command determines that deplaning passengers at a suitable disembarkation point would jeopardize passenger safety or security, or when there is a safety-related or security-related reason why the aircraft cannot leave its position on the tarmac to deplane passengers. A suitable disembarkation point is defined as a location at an airport where passengers have the ability to deplane from an aircraft. The Department's Enforcement Office already considers the exceptions provided in 49 U.S.C. 42301 and the Department's tarmac delay rule to determine whether a violation has occurred. As such, the Department does not anticipate that this change in language would impact carriers or consumers. Consistent with the statute and prior practice, under this proposal, a safety or security exception would apply when passengers are at a suitable disembarkation point to deplane but are unable to do so for an unavoidable safety-related reason such as lightning. If, however, the passengers are at a suitable disembarkation point such as a remote hardstand to deplane but are unable to do so because of lack of buses or stairs, the safety or security exception would not apply.

As this rulemaking would not have an effect on the safety or security exceptions articulated in the rule and the statute, this NPRM would not negatively impact safety.

5. Other Carrier Obligations

This rulemaking would clarify carrier obligations with respect to the provision of food and water. Currently, carriers must provide adequate food and potable water no later than two hours after the aircraft leaves the gate (in the case of a departure) or touches down (in the case of an arrival) if the aircraft remains on the tarmac, unless the pilot-in-command determines that safety or security considerations preclude such service. Because the obligation to provide food and water is triggered two hours after the aircraft leaves the gate, there are two separate start times for carriers' tarmac delay responsibilities. More specifically, for the purposes of calculating the length of a tarmac delay, a tarmac delay starts after the main aircraft door has closed in preparation for departure, which generally means that passengers on board the aircraft no longer have the opportunity to deplane. On the other hand, carriers' obligation to provide food and water occurs within two hours of the aircraft leaving the gate. The two start times are not always in alignment. For example, if an aircraft remains at the gate for one hour and passengers do not have the opportunity to deplane, and then the aircraft leaves the gate, the flight crew must maintain two separate timers, one to monitor the time of the tarmac delay, and the other to monitor the time since the aircraft left the gate to determine when food and water must be provided. This proposed rule would standardize carrier obligations such that the food and water timer would begin at the same time a tarmac delay begins. The proposed rule would also clarify that the food and water obligation only applies to situations in which the aircraft remains on the ground, both during departure and after touch-down.

The proposed rule would also change carrier obligations with respect to notifying passengers when they have an opportunity to deplane. Currently, carriers must provide notification to passengers that they have the opportunity to deplane from an aircraft if the opportunity to deplane exists. The first notification must be made beginning 30 minutes after the scheduled departure time and every 30 minutes thereafter while the opportunity to deplane exists. This proposed rule would eliminate the carrier's obligation to provide additional notifications every 30 minutes, thereby reducing the burden on carrier staff, while maintaining passengers' access to information. Carriers would be obligated to make a notification when an opportunity to deplane exists (and each time such an opportunity recurs, if, for

example, an aircraft returns to the gate after taxiing).

This rulemaking also proposes to eliminate the requirement that carriers provide notifications regarding the status and cause of the delay every 30 minutes to passengers on board an aircraft. The Department believes that the current rule, specifically the required frequency of notifications, provides no or limited value to passengers. It may even be harmful to passengers for carriers to provide frequent updates when the flight crew have no new updates to share with passengers and/or when passengers may be attempting to sleep during late night delays. The Department seeks comment on the elimination of this requirement.

Regulatory Notices

A. Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

This action has been determined to be nonsignificant under Executive Order 12866 (''Regulatory Planning and Review'') as supplemented by Executive Order 13563 (''Improving Regulation and Regulatory Review''). Accordingly, the Office of Management and Budget (OMB) has not reviewed it under that Order. It is also not significant under the Department of Transportation's Regulatory Policies and Procedures.

Nearly all the provisions in this proposed rule are deregulatory in nature, which would generate cost savings, or clarifications, which would result in no economic impact. Minimal costs may be associated with three provisions consisting of a requirement for carriers to: (1) Report the length of the excessive tarmac delay if the length is not otherwise represented by the data listed under 14 CFR 244.3(a); (2) collect a new data point for the start time of a tarmac delay for enforcement purposes for departing flights, which would be the time the main aircraft door closes; and (3) collect a new data point for the time carriers begin to return the aircraft to a suitable disembarkation point to deplane passengers on departing flights. The primary purpose of this proposed rule is to implement changes to the FAA Extension Act regarding carrier obligations during an excessive tarmac delay. In general, we expect the rule to generate cost savings and benefits to carriers and consumers due primarily to the new standard for departure delays. This rulemaking also includes provisions to make conforming changes to carrier tarmac delay reporting and record keeping requirements. The changes to record retention and reporting requirements would reduce the burden on carriers. However, these cost savings and benefits are minimal and difficult to quantify as annual tarmac delays are becoming relatively rare since the implementation of the 2009 Tarmac Delay rule. In particular, domestic tarmac delays have already been reduced to 193 in 2017 from 1,642 in 2007, or 2.2 delays dropping to 0.3 delays per 10,000 flights. Details are provided in the preliminary regulatory evaluation which is available in the docket.

B. Executive Order 13132 (Federalism)

This NPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). This NPRM does not propose any regulation that (1) has substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government, (2) imposes substantial direct compliance costs on State and local governments, or (3) preempts state law. States are already preempted from regulating in this area by the Airline Deregulation Act, 49 U.S.C. 41713. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

C. Executive Order 13084

This NPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Because none of the options on which we are seeking comment would significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13084 do not apply.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities. A direct air carrier or foreign air carrier is a small business if it provides air transportation only with small aircraft (*i.e.,* aircraft with up to 60 seats/18,000 pound payload capacity). See 14 CFR 399.73. Nearly all the provisions in this proposed rule are deregulatory in nature (which would generate cost savings) or clarifications (which would result in no economic impact). This NPRM's proposals are expected to result in cost savings or benefits that are minimal and difficult to quantify. A small number of tarmac delays occur on flights operated by small entities, and the impact on the small entities is expected to be minimal. Accordingly, the Department does not believe that the NPRM would have a significant impact on a substantial number of small entities. However, we invite comment on the potential impact of this rulemaking on small entities.

E. Paperwork Reduction Act

Under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) (PRA), no person is required to respond to a collection of information unless it displays a valid OMB control number. This NPRM proposes a revision to the existing information collection burdens under OMB control number 2105–0561. Under the PRA, before an agency seeks OMB approval for a proposed collection of information, it must first publish a document in the **Federal Register** providing 60-day notice to the public to allow for comment. The Department invites interested parties to comment on the information collection requirements contained in this document. As prescribed by the PRA, the requirement will not go into effect until OMB has approved them after a 30-day notice is issued and the Department has published a notice announcing the effective date of the revised information collection requirements.

This NPRM proposes to modify existing information collection requirements under OMB control number 2105–0561. This NPRM proposes changes to two parts of the Department's regulations: 14 CFR part 244 (reporting tarmac delay data) and part 259, specifically § 259.4(e) (retention of records related to tarmac delays). It would eliminate reports for tarmac delays between 3 and 4 hours on international flights, eliminate duplicative reporting of domestic tarmac delays that are already reported under 14 CFR part 234, and change a record retention requirement in 14 CFR 259.4(e) into a descriptive tarmac delay reporting requirement.

For each of the information collections proposed for 14 CFR part 244 and 14 CFR 259.4, the title, a description of the respondents, and an estimate of the burdens are set forth below:

1. *Requirement that carriers report certain tarmac delay data to BTS for tarmac delays exceeding 3 hours (for domestic flights) and exceeding 4 hours (for international flights) on a monthly basis.*

Title: Reporting Tarmac Delay Data to BTS for Tarmac Delays Exceeding 3

Hours (for Domestic Flights) and 4 Hours (for International Flights).

Respondents: U.S. carriers that operate scheduled passenger service or public charter service using any aircraft with 30 or more seats, and foreign air carriers that operate scheduled passenger or public charter service to and from the United States using any aircraft with 30 or more seats.

Number of Respondents: 61 U.S. and 70 foreign carriers (estimated). Due to the changes proposed by this NPRM, it is expected that in nearly all cases, tarmac delays that would be reportable under 14 CFR part 244 would be on international flights, as nearly all tarmac delays on domestic flights would be reported under 14 CFR part 234.[8] Based on data submitted by airlines to BTS from 2014 to 2018, we expect the NPRM's proposals to result in an average of 37 tarmac delays on international flights to be reported through BTS Form 244 in a given year.

Estimated Annual Burden on Respondents: Based on 2014–2018 data, the NPRM's proposals would result in 0 to 18 reports being filed under 14 CFR part 244 by U.S. air carriers each year, and 0 to 7 reports being filed under 14 CFR part 244 by foreign air carriers each year. This range reflects the lowest and highest number of reportable tarmac delays on international flights experienced by U.S. and foreign air carriers during the 2014–2018 period. At 30 minutes of burden per report filed, this proposal would result in a burden of between 0.0 hours and 9.0 hours for each U.S. carrier, and between 0.0 and 3.5 hours for foreign air carriers.

Estimated Total Annual Burden: As the proposals in this NPRM would result in an estimated 37 reports filed under 14 CFR part 244 each year, the total annual burden would be 1110 minutes (18.5 hours). This reflects a reduction in existing burdens that would result from the NPRM's proposals, including (1) elimination of reports for tarmac delays between 3 and 4 hours on international flights, and (2) elimination of duplicative reporting for domestic tarmac delays that are already reported under 14 CFR part 234. The NPRM's proposal to require an additional data point for certain tarmac delay reports (when the length of the tarmac delay is not reflected in the required data points reported on BTS Form 244) would not result in any measurable effect on burden.

2. Eliminating Tarmac Delay Record Retention Requirement and Adding a New Descriptive Reporting Requirement for Foreign Air Carriers.

Title: Changing Tarmac Delay Record Retention Requirement into a Descriptive Reporting Requirement That Complies with 49 U.S.C. 42301(h).

Respondents: U.S. carriers that operate scheduled passenger service or public charter service using any aircraft with 30 or more seats, and foreign air carriers that operate scheduled passenger or public charter service to and from the United States using any aircraft with 30 or more seats.

Number of Respondents: 61 U.S. air carriers and 70 foreign air carriers (estimated). Based on reports submitted by carriers to BTS between 2014 and 2018, we expect an average of 148 reportable tarmac delays to occur in a given year, with 128 operated by U.S. air carriers and 20 by foreign air carriers. Based on the NPRM's proposals, carriers would no longer need to retain for two years the records related to these tarmac delays. Instead, carriers would be required to file a report with a written description of the tarmac delay incident to the Department's Aviation Consumer Protection Division. Because U.S. carriers already file such reports pursuant to 49 U.S.C. 42301(h), U.S. carriers would not encounter any additional reporting burdens under the NPRM's proposed changes to 14 CFR 259.4, and would experience a net burden decrease as a result of the proposed elimination of the record retention requirement. Only the 20 tarmac delays operated by foreign air carriers would result in new reports being filed under 14 CFR 259.4.

Estimated Annual Burden on Respondents: We expect the burden on carriers to file descriptive tarmac delay reports is 2 hours per report for U.S. carriers and 4 hours per report for foreign carriers. As the NPRM only results in a new reporting burden for foreign air carriers, the expected burden per respondent is between 0 and 7 reports per year (based on the highest annual number of tarmac delays experienced by a single foreign carrier between 2014 and 2018), or 0.0 to 28.0 hours of burden per respondent. There will be no new burdens on U.S. air carriers under this information collection, due to U.S. air carriers' existing reporting requirement under 49 U.S.C. 42301(h).

Estimated Total Annual Burden: This information collection would result in an estimated annual burden of 20 reports, or 80 hours. This reflects a reduction in burden for U.S. carriers based on the elimination of the record retention burden required by 14 CFR 259.4(e).

The Department invites interested persons to submit comments on any aspect of each of these information collections, including the following: (1) The necessity and utility of the information collection, (2) the accuracy of the estimate of the burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) ways to minimize the burden of collection without reducing the quality of the collected information. Comments submitted in response to this NPRM will be summarized or included, or both, in the request for OMB approval of these information collections.

F. Unfunded Mandates Reform Act

The Department has determined that the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply to this NPRM.

G. National Environmental Policy Act

The Department has analyzed the environmental impacts of this proposed action pursuant to the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that it is categorically excluded pursuant to DOT Order 5610.1C, Procedures for Considering Environmental Impacts (44 FR 56420, Oct. 1, 1979). Categorical exclusions are actions identified in an agency's NEPA implementing procedures that do not normally have a significant impact on the environment and therefore do not require either an environmental assessment (EA) or environmental impact statement (EIS). See 40 CFR 1508.4. In analyzing the applicability of a categorical exclusion, the agency must also consider whether extraordinary circumstances are present that would warrant the preparation of an EA or EIS. Id. Paragraph 4(c)(6)(i) of DOT Order 5610.1C provides that ''actions relating to consumer protection, including regulations'' are categorically excluded. The purpose of this rulemaking is primarily to amend the definition of excessive tarmac delay. The Department does not anticipate any environmental impacts, and there are no extraordinary circumstances present in connection with this rulemaking.

List of Subjects

14 CFR Part 244

Administrative practice and procedure, Airports, Consumer protection.

[8] The NPRM would not affect the reporting of tarmac delays on domestic flights if those flights are not already reported under 14 CFR part 234 (*i.e.* those flights that are neither held out or operated by carriers that file reports under 14 CFR part 234); however, such tarmac delays are generally uncommon.

14 CFR Part 259

Air carriers, Consumer protection, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, DOT proposes to amend 14 CFR chapter II, subchapter A, as follows:

PART 244—REPORTING TARMAC DELAY DATA

■ 1. Revise the authority citation for part 244 to read as follows:

Authority: 49 U.S.C. 40101(a)(4), 40101(a)(9), 40113(a), 41702, 41712, and 42301.

■ 2. Amend § 244.1 by removing the definition of ''Arrival time'', adding definitions for ''Excessive tarmac delay'' and ''Gate arrival time'' in alphabetical order, and revising the definition for ''Tarmac delay'' to read as follows:

§ 244.1 Definitions.

* * * * *

Excessive tarmac delay means a tarmac delay of more than three hours for a domestic flight and more than four hours for an international flight.

* * * * *

Gate arrival time is the instant when the pilot sets the aircraft parking brake after arriving at the airport gate or passenger unloading area. If the parking brake is not set, record the time for the opening of the passenger door. Also, for purposes of § 244.3 carriers using a Docking Guidance System (DGS) may record the official ''gate-arrival time'' when the aircraft is stopped at the appropriate parking mark.

* * * * *

Tarmac delay means the period of time when an aircraft is on the ground with passengers and the passengers have no opportunity to deplane.

■ 3. Revise § 244.2 to read as follows:

§ 244.2 Applicability.

(a) *Covered operations.* Except as provided in paragraph (b) of this section, this part applies to U.S. certificated air carriers, U.S. commuter air carriers and foreign air carriers that operate passenger service to or from a U.S. airport with at least one aircraft that has an original manufacturer's design capacity of 30 or more seats. Covered carriers must report all passenger operations that experience an excessive tarmac delay at a U.S. airport.

(b) *Exceptions.* (1) For foreign air carriers that operate charter flights from foreign airports to U.S. airports, and return to foreign airports, and do not pick up any new passengers in the U.S., the charter flights are not flights subject to the reporting requirements of this part.

(2) For U.S. air carriers that submit Airline Service Quality Performance Reports under 14 CFR part 234, their scheduled domestic flights are not flights subject to the reporting requirements of this part to the extent part 234 reports are submitted for those flights.

■ 4. Revise § 244.3 to read as follows:

§ 244.3 Reporting of tarmac delay data.

(a) Each covered carrier shall file BTS Form 244 ''Tarmac Delay Report'' with the Office of Airline Information of the Department's Bureau of Transportation Statistics setting forth the information for each of its covered flights that experienced an excessive tarmac delay at a U.S. airport, including diverted flights and cancelled flights on which the passengers were boarded and then deplaned before the cancellation. The reports are due within 15 days after the end of any month during which the carrier experienced the excessive tarmac delay. The reports shall be made in the form and manner set forth in accounting and reporting directives issued by the Director, Office of Airline Information, and shall contain the following information:

(1) Carrier code.

(2) Flight number.

(3) Departure airport (three letter code).

(4) Arrival airport (three letter code).

(5) Date of flight operation (year/month/day).

(6) Gate departure time (actual) in local time.

(7) Wheels-off time (actual) in local time.

(8) Wheels-on time (actual) in local time.

(9) Gate arrival time (actual) in local time.

(10) Aircraft tail number.

(11) Total ground time away from gate for all gate return/fly return at origin airports including cancelled flights.

(12) Longest time away from gate for gate return or canceled flight.

(13) Three letter code of airport where flight diverted.

(14) Wheels-on time at diverted airport.

(15) Total time away from gate at diverted airport.

(16) Longest time away from gate at diverted airport.

(17) Wheels-off time at diverted airport.

(b) Covered carriers that experience an excessive tarmac delay at a U.S. airport and are filing a form under this section must also report the length of the excessive tarmac delay to the Office of Airline Information of the Department's Bureau of Transportation Statistics, if the length of the excessive tarmac delay experienced is not otherwise represented by the data points listed in paragraph (a) of this section (*e.g.,* the pilot sets the aircraft parking brake after arriving at the passenger unloading area, but passengers are not provided an opportunity to deplane at that time).

(c) The same information required by paragraphs (a)(13) through (17) of this section must be provided for each subsequent diverted airport landing.

PART 259—ENHANCED PROTECTIONS FOR AIRLINE PASSENGERS

■ 5. The authority citation for part 259 is revised to read as follows:

Authority: 49 U.S.C. 40101(a)(4), 40101(a)(9), 40113(a), 41702, 41712, and 42301.

■ 6. Revise § 259.2 to read as follows:

§ 259.2 Applicability.

This part applies to all the flights of a certificated or commuter air carrier if the carrier operates scheduled passenger service or public charter service using any aircraft originally designed to have a passenger capacity of 30 or more seats, and to all flights to and from the U.S. of a foreign air carrier if the carrier operates scheduled passenger service or public charter service to and from the U.S. using any aircraft originally designed to have a passenger capacity of 30 or more seats, except as otherwise provided in this part. This part does not apply to foreign air carrier charters that operate to and from the United States if no new passengers are picked up in the United States. Section 259.4 does not apply to a flight that diverts to the United States when the flight is operated by a foreign air carrier and scheduled to operate between two foreign points.

■ 7. Amend § 259.3 by adding definitions for ''Main aircraft door'' and ''Suitable disembarkation point'' in alphabetical order and revising the definition of ''Tarmac delay'' to read as follows:

§ 259.3 Definitions.

* * * * *

Main aircraft door means the door used for boarding. In situations in which there are multiple doors that can be used for boarding, the last door closed is considered the main aircraft door.

* * * * *

Suitable disembarkation point means a location at an airport where

passengers have the ability to deplane from an aircraft.

Tarmac delay means the period of time when an aircraft is on the ground with passengers and the passengers have no opportunity to deplane.

■ 8. Revise § 259.4 to read as follows:

§ 259.4 Contingency Plan for Lengthy Tarmac Delays.

(a) *Adoption of plan.* Each covered carrier, as defined by § 259.3, shall adopt a Contingency Plan for Lengthy Tarmac Delays for its scheduled and public charter flights at each U.S. large hub airport, medium hub airport, small hub airport, and non-hub airport at which it operates or markets such air service and shall adhere to its plan's terms.

(b) *Contents of plan.* Each Contingency Plan for Lengthy Tarmac Delays shall include, at a minimum, assurances that the covered carrier shall comply with the requirements set forth in paragraph (c) of this section.

(c) *Requirements.* Covered carriers must comply with the following requirements:

(1) For all domestic flights, each covered U.S. air carrier shall provide a passenger on a flight experiencing a tarmac delay at a U.S. airport the opportunity to deplane before the tarmac delay exceeds three hours in duration, subject to the exceptions in paragraph (c)(3) of this section;

(2) For all international flights, each covered carrier shall provide a passenger on a flight experiencing a tarmac delay at a U.S. airport the opportunity to deplane before the tarmac delay exceeds four hours in duration, subject to the exceptions in paragraph (c)(3) of this section;

(3) A covered U.S. carrier that experiences a tarmac delay at a U.S. airport must comply with paragraphs (c)(1) and (2) of this section, and a covered foreign air carrier must comply with paragraph (c)(2) of this section, unless:

(i) For departing flights, the flight begins to return to a suitable disembarkation point no later than three hours (for domestic flights) or four hours (for international flights) after the main aircraft door is closed in order to deplane passengers. If the aircraft is in an area that is not under the carrier's control, the aircraft has begun to return to a suitable disembarkation point when a request is made to the Federal Aviation Administration control tower, airport authority, or other relevant authority directing the aircraft's operations. If the aircraft is in an area that is under the carrier's control, the aircraft has begun to return to a suitable disembarkation point when the pilot begins maneuvering the aircraft to a suitable disembarkation point;

(ii) The pilot-in-command determines that deplaning passengers at a suitable disembarkation point would jeopardize passenger safety or security, or there is a safety-related or security-related reason why the aircraft cannot leave its position on the tarmac to deplane passengers; or

(iii) Air traffic control advises the pilot-in-command that returning to a suitable disembarkation point to deplane passengers would significantly disrupt airport operations;

(4) For all flights if the aircraft remains on the tarmac, each covered carrier must provide adequate food and potable water no later than two hours after the main aircraft door is closed (in the case of a departure) or touches down (in the case of an arrival), unless the pilot-in-command determines that safety or security considerations preclude such service;

(5) For all flights, each covered carrier must ensure operable lavatory facilities, as well as adequate medical attention if needed, during a tarmac delay;

(6) For all flights, when the opportunity to deplane exists at a suitable disembarkation point, each covered carrier must notify the passengers on board the aircraft that they have the opportunity to deplane;

(7) Each covered carrier must ensure that it has sufficient resources to implement its Contingency Plan for Lengthy Tarmac Delays, as set forth in paragraphs (a) and (b) of this section; and

(8) Each covered carrier must ensure that its Contingency Plan for Lengthy Tarmac Delays, as set forth in paragraphs (a) and (b) of this section, has been coordinated with the following entities:

(i) Airport authorities (including terminal facility operators where applicable) at each U.S. large hub airport, medium hub airport, small hub airport, and non-hub airport that the carrier serves, as well as its regular U.S. diversion airports;

(ii) U.S. Customs and Border Protection (CBP) at each large U.S. hub airport, medium hub airport, small hub airport, and non-hub airport that is regularly used for that carrier's international flights, including regular U.S. diversion airports; and

(iii) The Transportation Security Administration (TSA) at each U.S. large hub airport, medium hub airport, small hub airport, and non-hub airport that the carrier serves, including regular U.S. diversion airports.

(d) *Diversions.* For purposes of this section, a diverted flight is treated as an arriving flight up to the point that an opportunity to deplane is provided to passengers. Once an opportunity to deplane is provided, the diversion is treated as a departing flight, and after that point, the departure delay exception in paragraph (c)(3)(i) of this section applies if the carrier begins to return to a suitable disembarkation point in order to deplane passengers.

(e) *Code-share responsibility.* The tarmac delay contingency plan of the carrier under whose code the service is marketed governs, if different from the operating carrier, unless the marketing carrier specifies in its contract of carriage that the operating carrier's plan governs.

(f) *Amendment of plan.* At any time, a carrier may amend its Contingency Plan for Lengthy Tarmac Delays to decrease the time for aircraft to remain on the tarmac for domestic flights covered in paragraph (c)(1) of this section, for aircraft to remain on the tarmac for international flights covered in paragraph (c)(2) of this section, for aircraft to begin to return to a suitable disembarkation point covered in paragraph (c)(3)(i) of this section, and for providing food and water covered in paragraph (c)(4) of this section. A carrier may also amend its plan to increase these intervals (up to the limits in this part), in which case the amended plan shall apply only to departures that are first offered for sale after the plan's amendment.

(g) *Written reports.* (1) Each covered operating carrier subject to this part shall submit to the Aviation Consumer Protection Division of the U.S. Department of Transportation a written description of each of the flights it operates that experiences a tarmac delay of more than three hours (on domestic flights) and more than four hours (on international flights) at a U.S. airport no later than 30 days after the tarmac delay occurs.

(2) The written description referenced in paragraph (g)(1) of this section shall include, at a minimum, the following information:

(i) The name of the operating carrier, the name of the marketing carrier if the operating carrier is not the marketing carrier, and the flight number;

(ii) The originally scheduled origin and destination airports of the flight;

(iii) The airport at which the tarmac delay occurred and the date it occurred;

(iv) The length of the tarmac delay that occurred; and

(v) An explanation of the incident, including the precise cause of the tarmac delay, the actions taken to

minimize hardships for passengers (including the provision of food and water, the maintenance and servicing of lavatories, and medical assistance), and the resolution of the incident.

(3) The written description referenced in paragraph (g)(1) of this section shall be accompanied by a signed certification statement that reads as follows:

I, (Name) and (Title), of (Air Carrier Name), certify that the enclosed report is, to the best of my knowledge and belief, true and correct.

Date:

Signature:

Name (Please Print or Type):

(4) A U.S. air carrier that submits a report in accordance with paragraph (g) of this section is in compliance with the reporting mandate for U.S. air carriers in 49 U.S.C. 42301(h) with respect to the excessive tarmac delay reported.

(h) *Unfair and deceptive practice.* A carrier's failure to comply with the assurances required by this part and contained in its Contingency Plan for Lengthy Tarmac Delays will be considered to be an unfair and deceptive practice within the meaning of 49 U.S.C. 41712 that is subject to enforcement action by the Department.

Issued this 15th day of October, 2019, in Washington, DC.

Elaine L. Chao,

Secretary of Transportation.

[FR Doc. 2019–22973 Filed 10–24–19; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 191018–0066]

RIN 0648–BI33

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery of the South Atlantic Region; Regulatory Amendment 26

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement recreational sector management measures described in Vision Blueprint Recreational Regulatory Amendment 26 (Regulatory Amendment 26) to the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (Snapper-Grouper FMP), as prepared and submitted by the South Atlantic Fishery Management Council (Council). For the recreational sector, this proposed rule would remove the minimum size limits for queen snapper, silk snapper, and blackfin snapper, reduce the minimum size limit for gray triggerfish in the exclusive economic zone (EEZ) off the east coast of Florida, and modify the 20-fish snapper-grouper aggregate bag limit. The purpose of this proposed rule is to minimize regulatory discards to the extent practicable, improve regulatory compliance among fishers, and increase consistency among regulations.

DATES: Written comments on the proposed rule must be received by November 25, 2019.

ADDRESSES: You may submit comments on the proposed rule, identified by ''NOAA–NMFS–2019–0077,'' by either of the following methods:

- *Electronic submission:* Submit all electronic comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/docket?D=NOAA-NMFS-2019-0077, click the ''Comment Now!''* icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Mary Vara, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in required fields if you wish to remain anonymous).

Electronic copies of Regulatory Amendment 26 may be obtained from *www.regulations.gov* or the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/regulatory-amendment-26-vision-blueprint-recreational-measures.* Regulatory Amendment 26 includes an environmental assessment, a regulatory impact review, and a Regulatory Flexibility Act (RFA) analysis.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery in the South Atlantic region is managed under the Snapper-Grouper FMP and includes queen snapper, silk snapper, blackfin snapper, and gray triggerfish, along with other snapper-grouper species. The Snapper-Grouper FMP was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Background

During a series of stakeholder meetings in 2014, the Council gathered input from recreational and commercial fishers throughout the South Atlantic region to develop a long-term strategic plan for managing the snapper-grouper fishery. Based on that input, the Council developed the 2016–2020 Vision Blueprint for the Snapper-Grouper Fishery (Vision Blueprint). The Vision Blueprint identified the goals, objectives, strategies, and actions that support the Council's vision for the snapper-grouper fishery and centers around four goal areas: Science, Management, Communication, and Governance. In 2015, the Council prioritized action items in the Vision Blueprint that would be addressed through amendments to the Snapper-Grouper FMP over the next 5 years. As part of this prioritization, the Council chose to focus on actions that would address the seasonality of access to certain snapper-grouper species and measures in order to lengthen fishing seasons and better utilize existing annual catch limits (ACLs) in the snapper-grouper fishery. To accomplish this, the Council began development of two regulatory amendments to the Snapper-Grouper FMP to address the commercial and recreational sectors, respectively. Regulatory Amendment 26 includes modifications to recreational sector management measures in the snapper-grouper fishery based on stakeholder input. The purpose of the Council's actions in Regulatory Amendment 26 is to reduce regulatory discards, improve regulatory compliance among fishers, and increase consistency among regulations. Separately, the Council has submitted to NMFS the Vision Blueprint Commercial Regulatory Amendment 27 to the Snapper-Grouper FMP, which would revise commercial management measures in the snapper-grouper fishery, and it is currently in the rulemaking process.

Management Measures Contained in This Proposed Rule

For the recreational sector, this proposed rule would remove the minimum size limits for silk snapper, queen snapper, and blackfin snapper, reduce the minimum size limit for gray triggerfish in the EEZ off the east coast of Florida, and modify the snapper-grouper aggregate bag limit for the 20-fish aggregate.

Minimum Size Limit for Queen Snapper, Silk Snapper, and Blackfin Snapper

The deep-water complex includes yellowedge grouper, silk snapper, misty grouper, queen snapper, sand tilefish, and blackfin snapper. This proposed rule would remove the 12 inches (30.5 cm) total length (TL) recreational minimum size limit for queen snapper, silk snapper, and blackfin snapper. The remaining species in the deep-water complex do not have a minimum size limit requirement. The current 12 inches (30.5 cm) TL minimum size limit for queen snapper, silk snapper, and blackfin snapper was implemented early in the management of the snapper-grouper fishery through Amendment 4 to the Snapper-Grouper FMP (56 FR 56016; October 31, 1991), before estimates of discard mortality were available, and prior to the creation of the various snapper-grouper species complexes by the Council. All of the species in the deep-water complex have high discard mortality as a result of the effects of barotrauma from being harvested from deep water. NMFS expects that removing the recreational minimum size limits would reduce discards and, therefore, discard mortality.

Minimum Size Limit for Gray Triggerfish

The current recreational minimum size limit for gray triggerfish in the South Atlantic EEZ off the east coast of Florida is 14 inches (35.6 cm) fork length (FL) and 12 inches (30.5 cm) FL, off North Carolina, South Carolina, and Georgia. This proposed rule would reduce the recreational minimum size limit for gray triggerfish to 12 inches (30.5 cm) FL in the EEZ off the east coast of Florida. In 2015, the 12-inch (30.5-cm) FL minimum size limit was implemented for gray triggerfish in the EEZ off North Carolina, South Carolina, and Georgia, and a minimum size limit of 14 inches (35.6 cm) FL was implemented in the EEZ off the east coast of Florida (80 FR 30947; June 1, 2015). This was a precautionary action taken by the Council in response to their concerns about the status of the South Atlantic gray triggerfish stock, to align Federal regulations off the east coast of Florida with those in the Gulf of Mexico, and to achieve consistency between state and Federal regulations off the east coast of Florida. However, after the minimum size limit went into effect on July 1, 2015, stakeholders in Florida expressed concern to the Florida Fish and Wildlife Conservation Commission (FWC) regarding an increasing number of gray triggerfish discards in south Florida where the average size of gray triggerfish is smaller than off northeast Florida. In response to that concern, the FWC reduced the recreational minimum size limit of gray triggerfish in Florida state waters from 14 inches (35.6 cm), FL to 12 inches (30.5 cm) FL in 2017, and requested that the Council develop consistent size limit regulations in Federal waters. Reducing the recreational minimum size limit to 12 inches (30.5 cm) FL would make the state and Federal regulations for gray triggerfish consistent off the east coast of Florida, and for all Federal waters throughout the Council's jurisdiction. NMFS expects this action to reduce regulatory discards, improve regulatory compliance among fishers, and increase consistency among regulations.

20-Fish Snapper-Grouper Aggregate Bag Limit

This proposed rule would modify the 20-fish snapper-grouper aggregate bag limit by specifying that no more than 10 fish can be of any one species within the 20-fish aggregate. Currently, 14 snapper-grouper species are included in the 20-fish aggregate bag limit for the recreational sector. Recreational fishers in the South Atlantic EEZ may retain 20 total fish per person per day for the following species: Whitebone porgy, jolthead porgy, knobbed porgy, saucereye porgy, scup, gray triggerfish, bar jack, almaco jack, banded rudderfish, lesser amberjack, white grunt, margate, sailor's choice, and Atlantic spadefish. These species do not have individual recreational bag limits. The Council determined that modifying the 20-fish aggregate bag limit in this way would allow recreational anglers to catch the same number of fish overall as within the current limit, while limiting the number of any one species within the 20-fish aggregate to 10 fish. Because of stakeholder concerns over the status of the South Atlantic gray triggerfish stock and large catches of Atlantic spadefish in recent years, the Council chose to be proactive and limit the harvest of these two species, as well as the remainder of the species in the 20-fish aggregate. In addition, the state of Florida currently limits harvest of gray triggerfish to 10 fish per person per day in state waters off its east coast. Therefore, this action to revise the snapper-grouper 20-fish aggregate bag limit would also simplify the regulatory environment by creating consistent regulations for recreational fishing for and retention of gray triggerfish in state and Federal waters off the east coast of Florida. In both cases (the size limits for gray triggerfish, and the bag limits applicable to gray triggerfish), the changes in this proposed rule would align the state and Federal regulations for gray triggerfish off the east coast of Florida.

Measures in Regulatory Amendment 26 Not in This Proposed Rule

During development of Regulatory Amendment 26, the Council considered three related actions that would establish a deep-water species aggregate, specify the recreational season for the deep-water species aggregate, and specify the aggregate bag limit for the deep-water species aggregate. Upon consideration, the Council decided not to make changes based on these three actions because of the regional and seasonal differences in access to some of the deep-water species in the South Atlantic and the potential disproportionate negative effects on some recreational fishers.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator has determined that this proposed rule is consistent with Regulatory Amendment 26, the Snapper-Grouper FMP, the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed 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 E.O. 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration for purposes of the RFA that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows.

A description of the proposed rule and its purpose are contained at the beginning of the **SUPPLEMENTARY INFORMATION** section and in the **SUMMARY** section of the preamble. The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative,

overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record keeping, or other compliance requirements are introduced by this proposed rule. Accordingly, this proposed rule does not implicate the Paperwork Reduction Act.

The proposed action would apply only to the recreational sector of the South Atlantic snapper-grouper fishery. This proposed action would remove the recreational minimum size limits for queen snapper, silk snapper, and blackfin snapper; reduce the recreational minimum size limit for gray triggerfish in the EEZ off the east coast of Florida; and modify the snapper-grouper 20-fish aggregate bag limit.

Recreational anglers fishing for snapper-grouper species would be directly affected by the proposed action, but anglers are not considered business entities under the RFA. For-hire vessels (charter vessels and headboats) would also be affected by this action, but only in an indirect way. For-hire businesses operate in the recreational sector, but these businesses only sell fishing services to recreational anglers. Even though expectations of successful fishing, however defined, likely factor into the decision by anglers to purchase these services, for-hire vessels provide a platform for the opportunity to fish and not a guarantee to catch or harvest any species. Because the effects on for-hire vessels would be indirect, they are outside the scope of the RFA. Therefore, the proposed actions in Regulatory Amendment 26 would not directly affect any small business entities in the snapper-grouper fishery.

Primarily for informational purposes to the public in this proposed rule, the following description of small entities (*i.e.,* for-hire vessels) indirectly affected by the proposed action is provided. Charter vessels and headboats (also called party boats) are the two types of vessels operating in the for-hire business industry. Although charter vessels tend to be smaller, on average, than headboats, the key distinction between the two types of operations is how the fee is typically determined. On a charter vessels trip, the fee charged is for the entire vessel, regardless of how many passengers are carried, whereas the fee charged for a headboat trip is paid per individual angler.

A Federal charter vessel/headboat snapper-grouper permit (South Atlantic for-hire permit) is required for harvesting snapper-grouper species when fishing on for-hire vessels. The South Atlantic for-hire permit is an open access permit. As of June 2, 2019, there were 1,743 valid (non-expired) or renewable South Atlantic for-hire permits. A renewable permit is an expired permit that may not be actively fished, but is renewable for up to 1 year after expiration. Some vessel owners may have obtained open access permits as insurance for uncertainties in the fisheries in which they currently operate. From 2012 through 2016, the lowest number of for-hire vessel permits occurred in 2014 and the highest occurred in 2016. The majority of snapper-grouper for-hire permitted vessels were home-ported in Florida, and approximately 10 percent of the total number of for-hire snapper-grouper vessels are home-ported in states outside of the Council's area of jurisdiction. Although the for-hire permit application collects information on the primary method of operation, the resultant permit itself does not identify the permitted vessel as either a charter vessel or a headboat. This is because operation as either a charter vessel or headboat is not restricted by the permitting regulations, and vessels may operate in both capacities under the permit. However, according to the NMFS Southeast Region Headboat Survey, there were 63 headboats operating in the South Atlantic.

Economic value for for-hire vessels can be measured by producer surplus (PS) per passenger trip (the amount of money that a vessel owner earns in excess of the cost of providing the trip). Estimates of the PS per for-hire passenger trip are not available. Instead, net operating revenue (NOR), which is the return used to pay all labor wages, returns to capital and owner profits, is used as a proxy for PS. For the South Atlantic region, estimated NOR values are $165 per charter angler trip and $45 per headboat angler trip. To calculate the economic effects on for-hire vessels, these NOR values would have to be multiplied by the changes in for-hire angler trips. Due to the absence of data regarding the complex nature of angler behavior, it is not possible to estimate the potential changes in angler trips. However, it is likely that for-hire trips would not be substantially reduced because of the presence of alternative species that anglers can target and catch. It is, therefore, likely that the NOR effects on for-hire vessels would be relatively small.

Regulatory Amendment 26 also considered three related actions that would have established a deep-water species aggregate, specified the recreational season for the deep-water species aggregate, and specified the aggregate bag limit for the deep-water species aggregate. Because the Council chose the no action alternative for each of these actions, they would have no economic effects on directly or indirectly affected small entities.

The information provided above supports a determination that this proposed rule would not directly affect any small entities in the snapper grouper fishery, and that it would not likely have a significant economic impact on even indirectly affected entities. Therefore, this proposed rule would not have a significant economic impact on a substantial number of small entities. Because this proposed rule, if implemented, is not expected to have a significant economic impact on any small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 622

Bag limits, Fisheries, Fishing, Grouper, Size limits, Snapper, South Atlantic.

Dated: October 21, 2019.

Samuel D. Rauch, III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.185, revise paragraphs (a)(3) and (c)(2) to read as follows:

§ 622.185 Size limits.

* * * * *

(a) * * *

(3) *Cubera, gray, and yellowtail snappers*—12 inches (30.5 cm), TL.

* * * * *

(c) * * *

(2) *Gray triggerfish*—12 inches (30.5 cm), FL.

* * * * *

■ 3. In § 622.187, revise paragraph (b)(8) to read as follows:

§ 622.187 Bag and possession limits.

* * * * *

(8) *South Atlantic snapper-grouper (whitebone porgy, jolthead porgy, knobbed porgy, saucereye porgy, scup, almaco jack, banded rudderfish, lesser amberjack, white grunt, margate, sailor's choice, Atlantic spadefish, gray triggerfish, bar jack), combined*—20. However, excluded from this 20-fish bag limit are tomtate, South Atlantic snapper-grouper ecosystem component species (specified in Table 4 of

Appendix A to part 622), and those specified in paragraphs (b)(1) through (7) and paragraphs (b)(9) and (10) of this section. Within the 20-fish bag limit, no more than 10 fish can be of any one of these single snapper-grouper species.

* * * * *

[FR Doc. 2019–23267 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 84, No. 207

Friday, October 25, 2019

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–DA–19–0094]

Notice of Request for Extension and Revision of a Currently Approved Information Collection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of request for extension and revision of a currently approved information collection.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Marketing Service's (AMS) intention to request approval, from the Office of Management and Budget, for an extension of and revision to the currently approved information collection for report forms under the Federal milk marketing order program.

DATES: Comments on this notice must be received by December 24, 2019 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments electronically at *http://www.regulations.gov* or to the Office of the Deputy Administrator, Dairy Program, AMS, USDA, 1400 Independence Avenue SW, Room 2968 South, Stop 0225, Washington, DC 20250–0225. Comments should make reference to the date and page number of this issue of the **Federal Register**. All comments will be posted electronically without change; including any personal information provided at *http://regulations.gov.* Comments will also be available for public inspection in the above office during regular business hours.

Additional Information or Comments: Contact Janel Barsi, Director, Order Operation and Accountability Division, Dairy Program, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, Room 2968 South, Stop 0225, Washington, DC 20250–0225.

SUPPLEMENTARY INFORMATION:

Title: Report Forms under Federal Milk Orders (From Milk Handlers and Milk Marketing Cooperatives).

OMB Number: 0581–0032.

Expiration Date of Approval: March 31, 2020.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: Federal milk marketing order regulations (7 CFR parts 1000–1199) authorized under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), require milk handlers to report in detail the receipts and utilization of milk and milk products handled at each of their plants that are regulated by a Federal order. The data are needed to administer the classified pricing system and related requirements of each Federal order.

A Federal milk marketing order (hereinafter, Order) is a regulation issued by the Secretary of Agriculture that places certain requirements on the handling of milk in the area it covers. Each Order is established under the authority of the Act. The Order requires that handlers of milk for a marketing area pay not less than certain minimum class prices according to how the milk is used. These prices are established under each Order after a public hearing at which evidence is received on the supply and demand conditions for milk in the market. An Order requires that payments for milk be pooled and paid to individual farmers or cooperative associations of farmers on the basis of a uniform or average price. Thus, all eligible farmers (producers) share in the market wide use-values of milk by regulated handlers.

Milk Orders help ensure adequate supplies of milk and dairy products for consumers and adequate returns to producers.

The Orders also provide for the public dissemination of market statistics and other information for the benefit of producers, handlers, and consumers.

Formal rulemaking amendments to the Orders must be approved in referenda conducted by the Secretary.

During 2018, 32,061 dairy farmers delivered over 141.7 billion pounds of milk to handlers regulated under the milk orders. This volume represents 65 percent of all milk marketed in the U.S. and 66 percent of the milk of bottling quality (Grade A) sold in the country. The value of this milk delivered to Federal milk order handlers at minimum order blend prices was over $21.9 billion. Producer deliveries of milk used in Class I products (mainly fluid milk products) totaled 40.9 billion pounds—28.9 percent of total producer deliveries.

Each Order is administered by a USDA market administrator. The market administrator is authorized to levy assessments on regulated handlers to carry out the market administrator's duties and responsibilities under the Orders. Additional duties of the market administrators are to prescribe reports required of each handler, to assure that handlers properly account for milk and milk products, and to assure that such handlers pay producers and associations of producers according to the provisions of the Order. The market administrator employs a staff that verifies handlers' reports by examining records to determine that the required payments are made to producers. Most reports required from handlers are submitted monthly to the market administrator.

The forms used by the market administrators are required by the respective Orders that are authorized by the Act. The forms are used to establish the quantity of milk received by handlers, the pooling status of the handlers, the class-use of the milk used by the handler, and the butterfat content and amounts of other components of the milk.

The forms covered under this information collection require the minimum information necessary to effectively carry out the requirements of the Orders, and their use is necessary to fulfill the intent of the Act as expressed in the Orders and in the rules and regulations issued under the Orders. The information collected is used only by authorized employees of the market administrator and authorized representatives of the USDA, including AMS Dairy Programs' headquarters staff.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .57 hours per response.

Respondents: Milk handlers and milk marketing cooperatives.

Estimated Number of Respondents: 745.

Estimated Total Annual Responses: 49,919.

Estimated Number of Responses per Respondent: 67.

Estimated Total Annual Burden on Respondents: 28,471 (rounded).

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 the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Dated: October 21, 2019.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2019–23239 Filed 10–24–19; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 22, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques and other forms of information technology.

Comments regarding this information collection received by November 25, 2019 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 20503. Commentors 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) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Forest Service

Title: Annual Wildfire Summary Report.

OMB Control Number: 0596–0025.

Summary of Collection: The Cooperative Forestry Assistance Act of 1978 (16 U.S.C. 2101) requires the Forest Service (FS) to collect information about wildfire suppression efforts by State and local fire fighting agencies in order to support specific congressional funding requests for the Forest Service State and Private Forestry Cooperative Fire Program. The program provides supplemental funding for State and local firefighting agencies. The FS works cooperatively with State and local fire fighting agencies to support their fire suppression efforts. FS will collect information using form FS 3100–8, Annual Wildfire Summary Report.

Need and Use of the Information: FS will collect information using form FS–3100–8 to determine if the Cooperative Fire Program funds, provided to the State and local fire fighting agencies have been used by State and local agencies to improve their fire suppression capabilities. The information collected includes the numbers of fires and acres burned on State and private land by cause, such as lightning, campfires, smoking, debris burning, arson, equipment, railroads, children and miscellaneous activities. Information about the importance of the State and Private Cooperative Fire Program will be shared with the pubic. The form also collects information on numbers of fires and acres burned by size classes. FS would be unable to assess the effectiveness of the State and Private Forestry Cooperative Fire Program if the information provided on FS–3100–8, were not collected.

Description of Respondents: State, Local or Tribal Government.

Number of Respondents: 56.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 28.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–23303 Filed 10–24–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

October 22, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by November 25, 2019 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), *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.

Food and Nutrition Service

Title: Performance Reporting System, Management Evaluation.

OMB Control Number: 0584–0010.

Summary of Collection: The purpose of the Performance Reporting System is to ensure that each State agency and project area is operating the Supplemental Nutrition Assistance Program (SNAP) in accordance with the Act, regulations, and the State agency's Plan of Operation. Section 11 of the Food and Nutrition Act (the Act) of 2008 requires that State agencies maintain necessary records to ascertain that SNAP is operating in compliance with the Act and regulations and must make these records available to the Food and Nutrition Service (FNS) for inspection.

Need and Use of the Information: FNS will use the information to evaluate state agency operations and to collect information that is necessary to develop solutions to improve the State's administration of SNAP policy and procedures. Each State agency is required to submit one review schedule every one, two, or three years, depending on the project areas make-up of the state.

Description of Respondents: State, Local, or Tribal Government.

Number of Respondents: 53.

Frequency of Responses: Recordkeeping; Reporting: Annually.

Total Burden Hours: 491,172.

Food and Nutrition Service

Title: Seniors Farmers' Market Nutrition Program (SFMNP).

OMB Control Number: 0584–0541.

Summary of Collection: This submission is a revision of a currently approved collection which covers the reporting and recordkeeping burden associated with the Seniors Farmers' Market Nutrition Program, OMB #0584–0541. The Farm Security and Rural Investment Act of 2002 (the 2002 Farm Bill), Public Law 107–171, authorized the SFMNP as a competitive grant program beginning Fiscal Year (FY) 2003 and gave USDA the authority to develop Federal regulations guiding the administration of the SFMNP. The Agriculture Improvement Act of 2018, Public Law 115–334 (the 2018 Farm Bill), provided continued funding for the SFMNP through FY 2023. Federal regulations governing the SFMNP (7 Code of Federal Regulations, part 249) require that certain program-related information be collected and that full and complete records concerning SFMNP operations are maintained. The information reporting and recordkeeping burdens are necessary to ensure appropriate and efficient management of the SFMNP.

Need and Use of the Information: The information collected is used by USDA to manage, plan, evaluate, make decisions, and report on SFMNP program operations. FNS uses the information collection to assess how each SFMNP State agency operates; to ensure regulatory compliance of State agencies, local agencies, and farmers/farmers' markets/roadside stands/CSA programs; to make program management decisions; and to report to Congress as needed.

Description of Respondents: State, Local, or Tribal Governments; Individuals and Households; Small Businesses (authorized outlets).

Number of Respondents: 854,090.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 449,090.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–23306 Filed 10–24–19; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0053]

Concurrence With OIE Risk Designations for Bovine Spongiform Encephalopathy

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our preliminary concurrence with the World Organization for Animal Health's (OIE) bovine spongiform encephalopathy (BSE) risk designations for Ecuador and Serbia. The OIE recognizes Ecuador as being of controlled risk for BSE and Serbia as being of negligible risk for BSE. We are taking this action based on our review of information supporting the OIE's risk designations for these regions.

DATES: We will consider all comments that we receive on or before December 24, 2019.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0053.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0053, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0053* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Tracy McCracken, Staff Officer, Strategy & Policy, Regionalization Evaluation Services, 4700 River Road, Riverdale, MD 20737; phone (301) 851–3461; *Tracy.McCracken@usda.gov.*

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 92 subpart B, ''Importation of Animals and Animal Products; Procedures for Requesting BSE Risk Status Classification With Regard To Bovines'' (referred to below as the regulations), set forth the process by which the Animal and Plant Health Inspection Service (APHIS) classifies regions for bovine spongiform encephalopathy (BSE) risk. Section 92.5 of the regulations provides that all countries of the world are considered by APHIS to be in one of three BSE risk categories: Negligible risk, controlled risk, or undetermined risk. These risk categories are defined in § 92.1. Any region that is not classified by APHIS as presenting either negligible risk or controlled risk for BSE is considered to present an undetermined risk. The list of those regions classified by APHIS as having either negligible risk or controlled risk can be accessed on the APHIS website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.* The list can also be obtained by writing to APHIS at Regionalization Evaluation Services, 4700 River Road, Unit 38, Riverdale, MD 20737.

Under the regulations, APHIS may classify a region for BSE in one of two ways. One way is for regions that have not received a risk classification from the World Organization for Animal Health (OIE) to request classification by APHIS. The other way is for APHIS to concur with the classification given to a country or region by the OIE.

If the OIE has classified a region as either BSE negligible risk or BSE

controlled risk, APHIS will seek information to support concurrence with the OIE classification. This information may be publicly available information, or APHIS may request that regions supply the same information given to the OIE. APHIS will announce in the **Federal Register**, subject to public comment, its intent to concur with an OIE classification.

In accordance with this process, we are giving notice in this document that APHIS intends to concur with the OIE risk classifications of the following regions:

- *Regions of negligible risk for BSE:* Serbia.
- *Regions of controlled risk for BSE:* Ecuador.

The OIE recommendations regarding each of the above countries can be viewed at http://www.oie.int/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/. The conclusions of the OIE scientific commission for these regions can be viewed at *https://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/SCAD/A_SCAD_Feb2019.pdf* (page 71 for Ecuador and page 68 for Serbia).

After reviewing any comments we receive, we will announce our final determination regarding the BSE classification of these regions in the **Federal Register**, along with a discussion of and response to pertinent issues raised by commenters. If APHIS recognizes the OIE negligible BSE risk designation of Serbia and/or the controlled risk BSE designation of Ecuador, the Agency will include those regions of negligible risk or controlled risk for BSE, as applicable, that is available to the public on the Agency's website at *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.*

Authority: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 21st day of October 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–23343 Filed 10–24–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2019–0072]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Introduction of Organisms and Products Altered or Produced Through Genetic Engineering

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations for the introduction of organisms and products altered or produced through genetic engineering.

DATES: We will consider all comments that we receive on or before December 24, 2019.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0072.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2019–0072, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0072* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information regarding the regulations for the introduction of organisms and products altered or produced through genetic engineering, contact Ms. Cynthia A. Eck, Document Control Officer, Communications Group, BRS, APHIS, 4700 River Road, Unit 146, Riverdale, MD 20737; (301) 851–3892. For more detailed information on the information collection, contact Mr. Joseph Moxey, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: 7 CFR part 340; Introduction of Organisms and Products Altered or Produced Through Genetic Engineering.

OMB Control Number: 0579–0085.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*), the Secretary of Agriculture is authorized to prohibit or restrict the importation, entry, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction or the dissemination of a plant pest into the United States.

Under this authority, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has established regulations in 7 CFR part 340, ''Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests,'' that govern the introduction (importation, interstate movement, or release into the environment) of covered genetically engineered organisms and products (''regulated articles''). A permit must be obtained or a notification acknowledged before a regulated article may be introduced. The regulations set forth the permit application requirements and the notification procedures for the introduction of a regulated article and necessitate certain activities including APHIS-issued permits, petitions, appeals, labeling containers, applicants' field testing records, documentation for approved training programs, submission of protocols to ensure compliance, memorandums of understanding, grants, and recordkeeping.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 1.48 hours per response.

Respondents: State and Tribal government agricultural representatives and applicants from agricultural companies.

Estimated annual number of respondents: 483.

Estimated annual number of responses per respondent: 18.

Estimated annual number of responses: 8,780.

Estimated total annual burden on respondents: 12,983 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 21st day of October 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–23344 Filed 10–24–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Supplemental Nutrition Assistance Program: State Agency Options for Standard Utility Allowances and Self-Employment Income

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This collection is a revision of a currently approved collection. This information collection addresses the State agency reporting burden associated with the following State agency options under the Supplemental Nutrition Assistance Program (SNAP): Establishing and reviewing standard utility allowances (SUAs) and establishing methodology for offsetting cost of producing self-employment income.

DATES: Written comments must be received on or before December 24, 2019.

ADDRESSES: The Food and Nutrition Service, USDA, invites interested persons to submit written comment.

- *Preferred Method:* Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.
- *Mail:* Send comments to Certification Policy Branch, Program Development Division, FNS, 3101 Park Center Drive, Alexandria, Virginia 22302.

All responses to this notice will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to the Certification Policy Branch, Program Development Division, FNS, 3101 Park Center Drive, Alexandria, Virginia 22302 or via email to *SNAPCPBRules@usda.gov.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Title: Supplemental Nutrition Assistance Program: State Agency Options for Standard Utility Allowances and Self-Employment Income.

Form Number: None.

OMB Number: 0584–0496.

Expiration Date: March 31, 2020.

Type of Request: Revision of a currently approved collection.

Abstract: The information collection addresses the mandatory State agency information and burden estimates associated with the following State agency options under SNAP: Establishing and reviewing SUAs and establishing methodology for offsetting cost of producing self-employment income.

SNAP regulations at 7 CFR 273.9(d)(6)(iii) allow State agencies to establish SUAs in place of the actual utility costs incurred by a household. State agencies are required to review and adjust SUAs annually to reflect changes in the costs of utilities. States must provide the amounts of the standards to FNS when they have changed, and submit methodologies used in developing and updating standards to FNS for approval when the methodologies are updated or changed.

SNAP regulations at 7 CFR 273.11(b) allow for self-employment income to be reduced by the cost of producing such income. The regulations allow the State agencies, with approval from FNS, to establish the methodology for offsetting the costs of producing self-employment income, as long as the procedure does not increase program costs. Most State agencies provide methodology information on written letterhead and typically submit it via email. Once approved by FNS, States can use these methodologies to determine net self-employment income for SNAP eligibility purposes.

This notice invites comments on the revisions made to the State Agency Options information collection for SNAP to reflect changes in the number of States electing to establish a methodology for offsetting the costs of producing self-employment income. Based on information provided in the Fourteenth Edition of the SNAP State Options Report, published on May 31, 2018, FNS proposes increasing this figure from 21 State agencies to 23 State agencies since the previous information collection renewal.

Using FNS–388 and 388A (approved under OMB Control Number 0584–0594; expiration date: 09/30/2019 (currently going through OMB approval process).), States send aggregate level data on participation, benefits issued, and other basic program information to FNS using the Food Programs Reporting System (FPRS) at *https://fprs.fns.usda.gov.* This collection uses information submitted in these FNS approved forms as supplemental data. However, this collection is not seeking approval for burden hours associated with the use of these forms because the burden is already accounted for under OMB Control Number 0584–0594.

FNS is currently in the process of conducting a limited number of

consultations with State agencies and FNS staff regarding the accuracy of the burden estimates in this information collection, including the validity of the methodology and assumptions that were used to estimate the burden. The inputs from those consultations will be considered, along with the public comments received in response to this notice, as FNS finalizes the burden estimate to be included in the request for OMB for approval.

Affected Public: The respondent group identified includes 53 State agencies.

Estimated Number of Respondents: The total estimated number of respondents is 53.

Estimated Number of Responses per Respondent: FNS estimates 53 State agencies will submit one request each to adjust the SUA. Based on the information provided in the Fourteenth Edition of the SNAP State Options Report, out of the 53 State agencies, 23 State agencies have incorporated a methodology for determining the cost of doing business in self-employment cases. It is estimated that these 23 States will submit one request each, totaling 23 annual responses related to establishing a methodology for offsetting cost of producing self-employment income. All 53 State agencies are required to keep and maintain one record of the information gathered and submitted to FNS for the SUA and self-employment options. Therefore, it is estimated that each respondent will be responsible for 2.4340 responses.

Estimated Total Annual Responses: 129.

Estimated Time per Response: 5.9395 (hours).

Estimated Total Annual Burden on Respondents: 766.1957 (hours). See table below for estimated total annual burden for State agencies.

CFR citation	Respondent	Estimated number of respondents	Responses annually per respondent	Total annual responses	Estimated average number of hours per response	Estimated total hours
Reporting Burden						
7 CFR 273.9(d)(6)(iii)	State Agency—Review of SUA Submissions.	53	1	53	10	530
7 CFR 273.11(b)	State Agency—Review of Self-Employment Methodology.	23	1	23	10	230
	Total Reporting Burden	53		76		760
Recordkeeping Burden						
	State Agency	53	1	53	0.1169	6.1957
	Total Recordkeeping Burden.	53		53		6.1957
Total of Reporting and Recordkeeping Burden						
	Total	53		129		766.1957

Dated: October 7, 2019.

Pamilyn Miller,

Administrator, Food and Nutrition Service.

[FR Doc. 2019–23217 Filed 10–24–19; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Revision of the Land Management Plan for Inyo National Forest

AGENCY: Forest Service, USDA.

ACTION: Notice of approval of the revised Land Management Plan for the Inyo National Forest.

SUMMARY: Tammy Randall-Parker, the Forest Supervisor for Inyo National Forest, Pacific Southwest Region, has signed the Record of Decision (ROD) for the revised Inyo National Forest Land Management Plan. The final ROD documents the rationale for approving the revised Land Management Plan and is consistent with the Reviewing Officer's response to objections and instructions.

DATES: The revised Land Managmenent Plan for Inyo National Forest will become effective 30 days after the publication of this notice of approval in the **Federal Register** (36 CFR 219.17(a)(1)). To view the final ROD, final environmental impact statement (FEIS), the revised Land Management Plan, and other related documents, please visit the Inyo National Forest website at: *www.fs.usda.gov/main/inyo/landmanagement/planning.*

A legal notice of approval is also being published in Inyo National Forest's newspaper of record, *the Inyo Register.* A copy of this legal notice will be posted on the website described above.

FOR FURTHER INFORMATION CONTACT: Further information about the revised Land Management Plan for Inyo National Forest can be obtained by contacting Erin Noesser, Forest National Environmental Policy Act (NEPA) coordinator, at (760) 873–2449. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern time, Monday through Friday. Written requests for information may be sent to *erin.noesser@usda.gov* or Inyo National Forest, Attn. INF Plan Revision, 351 Pacu Ln., Suite 200, Bishop, CA 93514.

SUPPLEMENTARY INFORMATION: The Inyo National Forest covers approximately two million acres in eastern California. The revised Land Management Plan, which was developed pursuant to the 2012 Forest Planning Rule (36 CFR 219), will replace the Land Management Plan approved in 1988 (including amendments). This new, revised Land Management Plan establishes a strong commitment to forest visitors and local

communities by providing a variety of social and economic benefits associated with an all-lands approach to conserving high-priority forest ecosystems. The plan components were developed using best available scientific information and the consideration of fiscal capability.

A draft ROD, revised Land Management Plan, and FEIS were released in August 2018, and were subject to a pre-decisional objection period. Twenty-two objections were received, and an in-person objection resolution meeting was held in February 2019, with the Reviewing Officer and objectors in attendance. The Reviewing Officer's response to the objection has been signed by the Deputy Regional Forester for the Pacific Southwest Region. The instructions from the Reviewing Officer were incorporated into the final ROD. The final ROD to approve the revised Land Management Plan for Inyo National Forest has now been signed by the Responsible Official, and is available at the website described above.

Responsible Official

The responsible official for the revision of the Land Management Plan for the Inyo National Forest is Tammy Randall-Parker, Forest Supervisor, Inyo National Forest, 351 Pacu Ln., Suite 200, Bishop, CA 93514.

Dated: October 18, 2019.

Allen Rowley,

Associate Deputy Chief, National Forest System.

[FR Doc. 2019–23242 Filed 10–24–19; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Office of Partnerships and Public Engagement

Advisory Committee on Beginning Farmers and Ranchers

AGENCY: Office of Partnerships and Public Engagement (OPPE), U.S. Department of Agriculture (USDA).

ACTION: Announcement of Public Meeting of the Advisory Committee on Beginning Farmers and Ranchers (ACBFR).

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA) and rules and regulations of the USDA, the Office of Partnership and Public Engagement (OPPE) announces a meeting of the Advisory Committee on Beginning Farmers and Ranchers (ACBFR). The purpose of the ACBFR meeting is to deliberate upon matters concerning beginning farmers and ranchers that provide advice and recommendations through OPPE for the Secretary.

The most up-to-date agenda details and documents will be made available to the public before and after the meeting at: *https://www.outreach.usda.gov/committees/ACBFR.htm.*

DATES: The ACBFR meeting will be held on Thursday, October 31, 2019, at 9:00 a.m. to 5:00 p.m. (Eastern Time Zone) and on Friday, November 1, 2019 at 8:00 a.m. to 11:00 a.m. (Eastern Time Zone). An Executive Session—Administrative meeting (USDA and Committee Members only) will be held 11:15 a.m.–Noon.

ADDRESSES:

(a) *Attendance in-person:* Omni Severin Hotel, 40 W Jackson Pl, Indianapolis, IN 46225.

(b) *Public Call Information—Listen Only:* Dial: 866–816–7252 Conference ID: 6188761.

(c) *Comments may be sent to: ACBeginningFarmersandRanchers@usda.gov.*

FOR FURTHER INFORMATION CONTACT: Designated Federal Officer (DFO) Maria Goldberg, OPPE, 202–720–6350, or email: *maria.goldberg@usda.gov.*

This notice is being published less than 15 days prior to the meeting due to scheduling difficulties.

SUPPLEMENTARY INFORMATION: Members of the public are entitled to make comments during the public comment session. Commenters will be allowed a maximum of three minutes and will be scheduled on a first- come basis. If the number of persons requesting to speak is greater than what can be reasonably accommodated during the scheduled open public meeting timeframe; written comments may be submitted.

Written comments for the Committee's consideration may be submitted to Ms. Maria Goldberg, Designated Federal Officer, USDA OPPE, 1400 Independence Avenue, Room 533–A, Washington, DC 20250–0170; Fax (202) 720–7136; or email: *ACBeginningFarmersandRanchers@usda.gov.* Written comments must be received by OPPE within 30 days after the scheduled meeting.

Meeting Accommodations: USDA is committed to ensuring that all persons are included in our programs and events. If you are a person with a disability and require reasonable accommodations to participate in this meeting, please contact Maria Goldberg, 202–720–6350 or email: *maria.goldberg@usda.gov.*

Riley W. Pagett,

Chief of Staff, Office of Partnerships and Public Engagement, U.S. Department of Agriculture.

[FR Doc. 2019–23244 Filed 10–24–19; 8:45 am]

BILLING CODE 3412–89–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Pennsylvania Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of public meeting school discipline and school-to-prison pipeline in PA.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that a meeting of the Pennsylvania Advisory Committee to the Commission will convene in-person and via conference call at 9:00 a.m. to 5:00 p.m. (EST) on Thursday, November 21, 2019. The purpose of the briefing is for the Committee to receive testimony regarding disparate discipline and the school-to-prison pipeline in Pennsylvania.

DATES: Thursday, November 21, 2019, at 9:00 a.m. (EDT).

ADDRESSES: Temple University Center City, 1515 Market Street, Room 222, Philadelphia, PA 19202.

Public Call-In Information: Conference call-in number: 800–353–6461 and conference call ID number: 6813288.

FOR FURTHER INFORMATION CONTACT: Ivy Davis at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 800–353–6461 and conference call ID number: 6813288. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first

calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call-in number: 800–353–6461 and conference call ID number: 6813288.

Individuals attending the briefing in-person and requiring accommodations must contact Corrine Sanders 15 business days before the scheduled date by phone (202–768–54740) or by email (*csanders@usccr.gov*).

Members of the public are invited to make statements during the Public Comments section of the meeting—not to exceed five minutes—or to submit written comments. The comments must be received in the regional office approximately 30 days after the scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, or emailed to Corrine Sanders at *ero@usccr.gov.* Persons who desire additional information may phone the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at: *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzjZAAQ*; click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda

Thursday, November 21, 2019

Opening Remarks and Introductions (9:00 a.m.–9:15 a.m.)

Panel 1: (9:15 a.m.–10:45 a.m.)

Panel 2: (10:45 a.m.–12:15 p.m.)

Lunch break: (12:15 p.m.–1:00 p.m.)

Panel 3: (1:00 p.m.–2:30 p.m.)

Panel 4: (2:30 p.m.–4:00 p.m.)

Public Comments: (4:00 p.m.–5:00 p.m.)

Adjourn

Dated: October 21, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–23234 Filed 10–24–19; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Florida Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Florida Advisory Committee (Committee) will hold a meeting on Thursday, October 31, 2019, at 3:00 p.m. (EST). for the purpose of reviewing received testimony and discussing next steps in hearing testimony regarding Voters Suppression and Disenfranchisement Issues.

DATES: The meeting will be held on Thursday, October 31, 2019, at 3:00 p.m. (EST).

Public Call Information: Dial: 800–367–2403, Conference ID: 5151089.

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or 312–353–8311.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the toll-free call-in number dial: 800–367–2403, Conference ID: 5151089. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Written comments may be mailed to the Regional Program Unit Office, U.S. Commission on Civil Rights, 230 S Dearborn St., Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324 or may be emailed to the Regional Director, Jeff Hinton at *jhinton@usccr.gov.* Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Florida Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Program Unit at the above email or street address.

Agenda

Welcome and Roll Call

Discussion: Voters Suppression and Disenfranchisement Issues

Public Comment

Adjournment

Dated: October 21, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019–23275 Filed 10–24–19; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; Monthly Retail Surveys

AGENCY: U.S. Census Bureau, 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: To ensure consideration, written comments must be submitted on or before December 24, 2019.

ADDRESSES: Direct all written comments to Thomas Smith, PRA Liaison, U.S. Census Bureau, 4600 Silver Hill Road, Room 7K250A, Washington, DC 20233 (or via the internet at *PRAcomments@doc.gov*). You may also submit comments, identified by Docket Number USBC–2019–0014, to the Federal e-Rulemaking Portal: *http://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit

attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Paul Bucchioni, U.S. Census Bureau, EID HQ–8K181, 4600 Silver Hill Road, Washington, DC 20233–6500, (301) 763–7125 (or via the internet at *Paul.A.Bucchioni@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau plans to request an extension of the current Office of Management and Budget clearance for the surveys known as the Monthly Retail Trade Survey (MRTS) and the Advance Monthly Retail Trade Survey (MARTS). The MRTS and MARTS are related collections sharing the same initial sample frame and collect data that are published in conjunction with each other. Beginning with the previous clearance, these two surveys were combined under one control number 0607–0717 and are collectively called the Monthly Retail Surveys (MRS).

The Monthly Retail Trade Survey (MRTS) provides estimates of monthly retail sales, end-of-month merchandise inventories, and quarterly e-commerce sales for firms located in the United States and classified in the Retail Trade or Food Services sectors as defined by the North American Industry Classification System (NAICS).

Estimates produced from the MRTS are based on a probability sample of approximately 13,000 firms. The sample design consists of one fixed panel where all cases are requested to report sales, e-commerce sales, and/or inventories for the prior month. If reporting data for a period other than the calendar month, the survey asks for the period's length (4 or 5 weeks) and the date on which the period ended. The survey also asks for the number of establishments covered by the data provided and whether the sales data provided are estimates or more accurate ''book'' figures. The sample is drawn approximately every 5 years from the Business Register, which contains all Employer Identification Numbers (EINs) and listed establishment locations. The sample is updated quarterly to reflect employer business ''births'' and ''deaths''; adding new employer businesses identified in the Business and Professional Classification Survey (SQ–CLASS) and deleting firms and EINs when it is determined they are no longer active. Estimates from the MRTS are released in three different reports each month. High level aggregate estimates for end of month inventories are first released as part of the Advance Economic Indicators Report approximately four weeks after the close of the reference month. The sales and inventories estimates from MRTS are released approximately six weeks after the close of the reference month as part of the Monthly Retail Trade report and the Manufacturing and Trade Inventories and Sales (MTIS) report, which are released on the same day. Additionally, once per quarter, data for quarterly e-commerce sales are released approximately 50 days after the close of the reference quarter as part of the Quarterly Retail E-Commerce Sales report. Currently, there are no planned changes for MRTS.

The Advance Monthly Retail Trade Survey (MARTS) provides an early indication of monthly sales for retail trade and food services firms located in the United States. It was developed in response to requests by government, business, and other users to provide an early indication of current retail trade activity in the United States. Retail sales are one of the primary measures of consumer demand for both durable and non-durable goods. The MARTS survey results are published approximately two weeks after the end of the reference month. MARTS provide an OMB-designated Principal Federal Economic Indicator and the earliest available monthly estimates of broad-based retail trade activity. It also provides an estimate of monthly sales at food service establishments and drinking places.

The MARTS sample is a sub-sample of companies selected from the MRTS. The advance survey sample of about 5,500 companies are selected using a stratified sample by industry and size. Some 1,650 firms, because of their relatively large effect on the sales of certain industry groups, are selected with certainty. The MARTS sample is re-selected generally at 2½ to 3-year intervals to ensure it is representative of the target population and to redistribute burden for small- and medium-sized businesses.

Similarly to the MRTS sales estimates, advance sales estimates for each kind of business are developed by applying a ratio of current-month to previous-month sales (derived from the advance retail and food service sample) to the preliminary estimate of sales for the previous month (from the larger monthly sample). Industry estimates are summed to derive total retail sales figures.

The MARTS survey requests sales and e-commerce sales for the month just ending. As on the MRTS survey, if firms report data for a period other than the calendar month, the survey asks for the period's length (4 or 5 weeks) and the date on which the period ended. Also similar to MRTS, the survey also asks for the number of establishments covered by the data provided and whether the sales data provided are estimates or more accurate ''book'' figures. Currently, there are no planned changes for MARTS.

The Bureau of Economic Analysis (BEA) uses the information collected on these surveys to prepare the National Income and Products Accounts, to benchmark the annual input-output tables and as critical inputs to the calculation of the Gross Domestic Product (GDP). Policymakers at the Federal Reserve Board (FRB), the National Economic Council, and other federal and state governmental agencies as well as many private sector entities rely on the timely estimates of retail sales when making monetary and economic policy decisions.

II. Method of Collection

We collect this information primarily by internet. We do collect a small portion of the data by mail, FAX, and telephone follow-up.

III. Data

OMB Control Number: 0607–0717.

Form Number(s): SM–4417A–A, SM–4417A–E, SM–4417AE–A, SM–4417AE–E, SM–4417AS–A, SM–4417AS–E, SM–7217A–A, SM7217A–E, SM–4417S–A, SM–4417SE–A, SM–4417SSA, SM–7217S–A, SM–7217S–E, SM–4417S–E, SM–4417SE–E, SM–4417SS–E, SM–4417B–A, SM4417BE–A, SM–4417BS–A, SM–4417B–E, SM–4417BE–E, SM–4417BS–E, SM–2017I–A, SM–2017I–E.

Type of Review: Regular submission.

Affected Public: Retail and Food Services firms in the United States.

Estimated Number of Respondents: MRTS–13,000; MARTS–5,500.

Estimated Time per Response: MRTS–7 minutes; MARTS–5 minutes.

Estimated Total Annual Burden Hours: 18,200. (To eliminate duplication, firms that report to the MARTS survey are not required to provide sales and ecommerce sales information for MRTS. Therefore, we use the MRTS sample size and average burden per response to estimate the combined total annual burden for both surveys. The MRTS survey has the maximum number of questions for any given survey respondent as well as the longest estimated burden (at 7 min)).

Estimated Total Annual Cost to Public: $0. (This is not the cost of respondents' time, but the indirect costs

respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Section 131 and 182.

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.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–23327 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–42–2019]

Foreign-Trade Zone (FTZ) 92—Gulfport, Mississippi; Authorization of Production Activity; Vision Technologies Marine, Inc. (Ocean Going-Vessels: Compensators), Pascagoula, Mississippi

On June 19, 2019, Vision Technologies Marine, Inc. (Vision Tech) submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 92 in Pascagoula, Mississippi.

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 (84 FR 31293, July 1, 2019). On October 17, 2019, 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, except for the foreign-status component identified as ''tape'' due to insufficient information. The applicant may, however, submit another notification of proposed production activity with more detailed information for the foreign-status component in question.

Dated: October 17, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–23357 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–40–2019]

Foreign-Trade Zone (FTZ) 100—Dayton, Ohio; Authorization of Limited Production Activity; Whirlpool Corporation (Small Appliances); Greenville, Ohio

On June 19, 2019, Whirlpool Corporation submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 100, in Greenville, Ohio.

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 (84 FR 31021, June 28, 2019). On October 17, 2019, the applicant was notified of the FTZ Board's decision that further review of part of the proposed activity is warranted. The FTZ Board authorized the production activity described in the notification on a limited basis, subject to the FTZ Act and the Board's regulations, including Section 400.14, and further subject to a restriction requiring that non-woven cotton cloth bags be admitted to the subzone in privileged foreign status (19 CFR 146.41). Given the applicant's commitment in its notification, the following components must also be admitted to the subzone in privileged foreign status: Cotton cloth covers not knitted or crocheted; cotton cloth covers; cloth covers; and, lithium-ion batteries.

Dated: October 17, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–23351 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–43–2019]

Foreign-Trade Zone (FTZ) 176—Rockford, Illinois; Authorization of Production Activity; Staal & Plast USA, Inc. (Irrigation Trays); Sycamore, Illinois

On June 24, 2019, Staal & Plast USA, Inc., submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 176, in Sycamore, Illinois.

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 (84 FR 31833, July 3, 2019). On October 22, 2019, 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.

Dated: October 22, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–23356 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–215–2019]

Foreign-Trade Zone 186—Waterville, Maine; Application for Subzone Expansion; Flemish Master Weavers, Sanford, Maine

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the City of Waterville, grantee of FTZ 186, requesting an expansion of Subzone 186A on behalf of Flemish Master Weavers in Sanford, Maine. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on October 18, 2019.

Subzone 186A currently consists of the following site: Site 1 (6.4 acres) 96 Gatehouse Road, Sanford. The proposed expansion would add 0.5 acres to the existing site. No authorization for expanded production activity has been requested at this time. The subzone will be subject to the existing activation limit of FTZ 186.

In accordance with the Board's regulations, Elizabeth Whiteman of the

FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is December 4, 2019. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to December 19, 2019.

A copy of the application will be available for public inspection in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Elizabeth Whiteman at *Elizabeth .Whiteman@trade.gov* or (202) 482–0473.

Dated: October 21, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019–23358 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–065]

Stainless Steel Flanges From the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on stainless steel flanges from the People's Republic of China (China) for the period January 23, 2018, through December 31, 2018.

DATES: Applicable October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Nathan James, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5305.

SUPPLEMENTARY INFORMATION:

Background

On May 3, 2019, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the CVD order on stainless steel flanges from China for the period January 23, 2018, through December 31, 2018.[1] On July 1, 2019, Coalition of American Flange Producers, a domestic interested party, filed a timely request for review with respect to 46 companies, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b).[2] Pursuant to this request, and in accordance with section 751(a) of the Act and 19 CFR 351.221(c)(1)(i), we initiated an administrative review of these companies.[3] On September 9, 2019, Coalition of American Flange Producers filed a timely withdrawal of request for the administrative review of all 46 companies.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if the party that requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. As noted above, Coalition of American Flange Producers, the only party to file a request for review, withdrew its request by the 90-day deadline. Accordingly, we are rescinding the administrative review of the CVD order on stainless steel flanges from China for the period January 23, 2018, through December 31, 2018, in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries of stainless steel flanges from China. Countervailing duties shall be assessed at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of countervailing duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of countervailing duties occurred and the subsequent assessment of doubled countervailing duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to all 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. Timely written notification of the return/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 violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: October 21, 2019.

James Maeder,

Deputy Assistant Secretary

for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–23342 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 84 FR 25521 (June 3, 2019).

[2] *See* Letter from Coalition of American Flange Producers, ''Stainless Steel Flanges from the People's Republic of China: Request for Administrative Review,'' dated July 1, 2019.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 36572 (July 29, 2019).

[4] *See* Letter from Coalition of American Flange Producers, ''Stainless Steel Flanges from the People's Republic of China: Withdrawal of Request for Administrative Review,'' dated September 9, 2019.

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 84–30A12]

Export Trade Certificate of Review

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of issuance of an amended Export Trade Certificate of Review to Northwest Fruit Exporters (''NFE''), Application No. 84–30A12.

SUMMARY: The Secretary of Commerce, through the Office of Trade and Economic Analysis (''OTEA''), issued an amended Export Trade Certificate of Review (''Certificate'') to NFE on October 15, 2019.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, OTEA, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@ trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of

1982 (15 U.S.C. 4001–21) (''the Act'') authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325. OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the certification in the **Federal Register**. Under Section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

Description of Certified Content

NFE's Certificate was amended as follows:

1. Added the following company as a new Member of the Certificate within the meaning of section 325.2(l) of the Regulations (15 CFR 325.2(l)):

- FirstFruits Farms, LLC, Prescott, WA

2. Deleted the following companies as Members of the Certificate:

- Broetje Orchards LLC, Prescott, WA
- Ice Lakes LLC, East Wenatchee, WA
- Larson Fruit Co., Selah, WA
- C.M. Holtzinger Fruit Co., Inc., Yakima, WA

NFE's amended Certificate Membership is as follows:

1. Allan Bros., Naches, WA
2. AltaFresh L.L.C. dba Chelan Fresh Marketing, Chelan, WA
3. Apple House Warehouse & Storage, Inc., Brewster, WA
4. Apple King, L.L.C., Yakima, WA
5. Auvil Fruit Co., Inc., Orondo, WA
6. Baker Produce, Inc., Kennewick, WA
7. Blue Bird, Inc., Peshastin, WA
8. Blue Star Growers, Inc., Cashmere, WA
9. Borton & Sons, Inc., Yakima, WA
10. Brewster Heights Packing & Orchards, LP, Brewster, WA
11. Chelan Fruit Cooperative, Chelan, WA
12. Chiawana, Inc. dba Columbia Reach Pack, Yakima, WA
13. CMI Orchards LLC, Wenatchee, WA
14. Columbia Fruit Packers, Inc., Wenatchee, WA
15. Columbia Valley Fruit, L.L.C., Yakima, WA
16. Congdon Packing Co. L.L.C., Yakima, WA
17. Conrad & Adams Fruit L.L.C., Grandview, WA
18. Cowiche Growers, Inc., Cowiche, WA
19. CPC International Apple Company, Tieton, WA
20. Crane & Crane, Inc., Brewster, WA
21. Custom Apple Packers, Inc., Quincy, and Wenatchee, WA
22. Diamond Fruit Growers, Inc., Odell, OR
23. Domex Superfresh Growers LLC, Yakima, WA
24. Douglas Fruit Company, Inc., Pasco, WA
25. Dovex Export Company, Wenatchee, WA
26. Duckwall Fruit, Odell, OR
27. E. Brown & Sons, Inc., Milton-Freewater, OR
28. Evans Fruit Co., Inc., Yakima, WA
29. E.W. Brandt & Sons, Inc., Parker, WA
30. FirstFruits Farms, LLC, Prescott, WA
31. Frosty Packing Co., LLC, Yakima, WA
32. G&G Orchards, Inc., Yakima, WA
33. Gilbert Orchards, Inc., Yakima, WA
34. Hansen Fruit & Cold Storage Co., Inc., Yakima, WA
35. Henggeler Packing Co., Inc., Fruitland, ID
36. Highland Fruit Growers, Inc., Yakima, WA
37. HoneyBear Growers LLC, Brewster, WA
38. Honey Bear Tree Fruit Co LLC, Wenatchee, WA
39. Hood River Cherry Company, Hood River, OR
40. JackAss Mt. Ranch, Pasco, WA
41. Jenks Bros Cold Storage & Packing, Royal City, WA
42. Kershaw Fruit & Cold Storage, Co., Yakima, WA
43. L & M Companies, Union Gap, WA
44. Legacy Fruit Packers LLC, Wapato, WA
45. Manson Growers Cooperative, Manson, WA
46. Matson Fruit Company, Selah, WA
47. McDougall & Sons, Inc., Wenatchee, WA
48. Monson Fruit Co., Selah, WA
49. Morgan's of Washington dba Double Diamond Fruit, Quincy, WA
50. Naumes, Inc., Medford, OR
51. Northern Fruit Company, Inc., Wenatchee, WA
52. Olympic Fruit Co., Moxee, WA
53. Oneonta Trading Corp., Wenatchee, WA
54. Orchard View Farms, Inc., The Dalles, OR
55. Pacific Coast Cherry Packers, LLC, Yakima, WA
56. Peshastin Hi-Up Growers, Peshastin, WA
57. Piepel Premium Fruit Packing LLC, East Wenatchee, WA
58. Pine Canyon Growers LLC, Orondo, WA
59. Polehn Farms, Inc., The Dalles, OR
60. Price Cold Storage & Packing Co., Inc., Yakima, WA
61. Pride Packing Company LLC, Wapato, WA
62. Quincy Fresh Fruit Co., Quincy, WA
63. Rainier Fruit Company, Selah, WA
64. Roche Fruit, Ltd., Yakima, WA
65. Sage Fruit Company, L.L.C., Yakima, WA
66. Smith & Nelson, Inc., Tonasket, WA
67. Stadelman Fruit, L.L.C., Milton-Freewater, OR, and Zillah, WA
68. Stemilt Growers, LLC, Wenatchee, WA
69. Strand Apples, Inc., Cowiche, WA
70. Symms Fruit Ranch, Inc., Caldwell, ID
71. The Dalles Fruit Company, LLC, Dallesport, WA
72. Underwood Fruit & Warehouse Co., Bingen, WA
73. Valicoff Fruit Company Inc., Wapato, WA
74. Washington Cherry Growers, Peshastin, WA
75. Washington Fruit & Produce Co., Yakima, WA
76. Western Sweet Cherry Group, LLC, Yakima, WA
77. Whitby Farms, Inc. dba: Farm Boy Fruit Snacks LLC, Mesa, WA
78. WP Packing LLC, Wapato, WA
79. Yakima Fresh, Yakima, WA
80. Yakima Fruit & Cold Storage Co., Yakima, WA
81. Zirkle Fruit Company, Selah, WA

The effective date of the amendment is July 17, 2019, the date on which NFE's application to amend was deemed submitted.

Dated: October 21, 2019.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 2019–23233 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–850]

Certain Large Diameter Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Over 4½ Inches) From Japan: Rescission of Antidumping Duty Administrative Review: 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the

administrative review of the antidumping duty (AD) order on certain large diameter carbon and alloy seamless standard, line, and pressure pipe (over 4½ inches) from Japan for the period of review (POR) June 1, 2018 through May 31, 2019, based on the timely withdrawal of the request for review.

DATES: Applicable October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Dusten Hom, AD/CVD Operations, Office 1, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5075.

SUPPLEMENTARY INFORMATION:

Background

On June 3, 2019, Commerce published a notice of opportunity to request an administrative review of the antidumping duty order on certain large diameter carbon and alloy seamless standard, line, and pressure pipe (over 4½ inches) from Japan for the POR of June 1, 2018 through May 31, 2019.[1] United States Steel Corporation (U.S. Steel) timely filed requests for an administrative review of Denka Company Limited (Denka), Ebara Corporation (Ebara), JFE Steel Corporation (JFE Steel), Kaneka Corporation (Kaneka), Kawasaki Steel Corporation (Kawasaki Steel), Maruichi Kohan Limited (Maruichi), Metal One Tubular Products Incorporated (Metal One), Nippon Steel & Sumitomo Metal Corporation (N&S), Nippon Steel Corporation (Nippon Steel), NKK Tubes (NKK), Okaya & Company Limited (Okaya), Sumitomo Corporation (Sumitomo Corp.), Sumitomo Metal Industries Limited (Sumitomo Metal), Taiheiyo Cement Corporation (Taiheiyo), Vallourec & Sumitomo Tubos do Brasil Limitada (V&C), Vallourec Solucoes Tubulares do Brasil (Vallourec Solucoes), and Yamashin Industry Company (Yamashin), in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b).[2]

On July 29, 2019, pursuant to these requests, and in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice initiating an administrative review of the antidumping duty order on large diameter carbon and alloy seamless standard, line, and pressure pipe (over 4½ inches) from Japan with respect to Denka, Ebara, JFE Steel, Kaneka, Kawasaki Steel, Maruichi, Metal One, N&S, Nippon Steel, NKK, Okaya, Sumitomo Corp., Sumitomo Metal, Taiheiyo, V&C, Vallourec Solucoes, and Yamashin.[3] On October 4, 2019, U.S. Steel withdrew its request for an administrative review with respect to all of the companies for which it had requested a review.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraws the request within 90 days of the publication date of the notice of initiation of the requested review. U.S. Steel withdrew its request for review of Denka, Ebara, JFE Steel, Kaneka, Kawasaki Steel, Maruichi, Metal One, N&S, Nippon Steel, NKK, Okaya, Sumitomo Corp., Sumitomo Metal, Taiheiyo, V&C, Vallourec Solucoes, and Yamashin. U.S. Steel withdrew its request within 90 days of the publication date of the notice of initiation. No other parties requested an administrative review of the order. Therefore, in accordance with 19 CFR 351.213(d)(1), we are rescinding this review in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of large diameter carbon and alloy seamless standard, line, and pressure pipe (over 4½ inches) from Japan. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as a reminder to importers of their responsibility under 19 CFR 351.42(f)(2) to file a certificate regarding the reimbursement of AD duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of AD duties occurred and the subsequent assessment of doubled AD duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to all 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. Timely written notification of the return/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 violation which is subject to sanction.

This notice is issues and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: October 21, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–23340 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Antidumping or Countervailing Duty Order. Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 84 FR 25521 (June 3, 2019).

[2] *See* letter from U.S. Steel, ''Carbon and Alloy Seamless Standard line, and Pressure Pipe (Over 4½ Inches) from Japan: Request for Administrative Review of Antidumping Duty Order,'' dated June 28, 2019.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 36572 (July 29, 2019).

[4] *See* letter from U.S. Steel, ''Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Over 4.5 Inches) from Japan: Withdrawal of Request for Administrative Review of Antidumping Duty Order,'' dated October 4, 2019.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–111]

Vertical Metal File Cabinets From the People's Republic of China: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers and exporters of vertical metal file cabinets (file cabinets) from the People's Republic of China (China).

DATES: Applicable October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Kathryn Wallace, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6251.

SUPPLEMENTARY INFORMATION:

Background

On August 1, 2019, Commerce published the *Preliminary Determination* of this investigation in the **Federal Register**.[1] A complete summary of the events that occurred since Commerce published the *Preliminary Determination,* as well as a full discussion of the issues raised for this final determination, may be found in the Issues and Decision Memorandum.[2]

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 *https://access.trade.gov,* and is available to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version are identical in content.

As stated in the *Preliminary Determination,* the deadline for the final determination of this investigation is 75 days after the signature of the *Preliminary Determination,* or October 7, 2019.

Period of Investigation

The period of investigation (POI) is January 1, 2018 through December 31, 2018.

Scope of the Investigation

The products covered by this investigation are file cabinets from China. For a complete description of the scope of this investigation, *see* Appendix I of this notice.

Analysis of Subsidy Programs and Comments Received

Hirsch Industries, LLC, the petitioner was the only interested party to submit a case brief.[3] The issues raised in the petitioner's case brief are discussed in the Issues and Decision Memorandum.

Use of Adverse Facts Available

Commerce relied on ''facts otherwise available,'' including adverse facts available (AFA), for certain findings in the *Preliminary Determination.* For this final determination, we continue to find that adverse inferences are warranted in selecting from facts otherwise available with respect to the certain producers and/or exporters that received quantity and value questionnaires from Commerce, but did not respond, pursuant to section 776(a)–(b) of the Act.[4] Accordingly, we continue to find that these non-responsive companies are benefitting from countervailable subsidies from all programs identified in the Initiation Checklist (and *Preliminary Determination*).[5]

In addition, for this final determination, with respect to the GOC, we find it appropriate to rely on adverse inferences in selecting from among the facts otherwise available, pursuant to section 776(a)–(b) of the Act. We continue to rely on the sole information on the record, the Petition, to find that each of the programs identified in the Initiation Checklist (and *Preliminary Determination*) provides a financial contribution and is specific pursuant to sections 771(5)(B) and (D) and 771(5A) of the Act, respectively.[6]

For a full discussion of our application of AFA, *see* the Issues and Decision Memorandum.

Changes Since the Preliminary Determination

Based on the GOC's failure to respond to the questionnaire issued to it following the *Preliminary Determination* and our analysis of the comments received, we made certain changes to our specificity and financial contribution findings set forth in the *Preliminary Determination.* In addition, Commerce has revised the subsidy rate applied to the Provision of Zinc for Less Than Adequate Remuneration (LTAR) program in this final determination. For a discussion of these changes, *see* the Issues and Decision Memorandum.

All-Others Rate

In accordance with section 705(c)(5)(A) of the Act, Commerce shall determine an estimated all-others rate for companies not individually examined. Generally, under section 705(c)(5)(A)(i) of the Act, this rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any zero and *de minimis* rates and any rates based entirely on facts available under section 776 of the Act. However, section 705(c)(5)(A)(ii) of the Act provides that, where all countervailable subsidy rates established for the mandatory respondents are zero, *de minimis,* or based entirely on facts available, Commerce may use ''any reasonable method'' for assigning an all-others rate, including ''averaging the estimated average countervailable subsidy rates determined for the exporters and producers individually investigated.'' In this investigation, all rates are based entirely on facts available, pursuant to section 776 of the Act. We are relying on a simple average of the total AFA rates assigned to the non-responsive companies as the all-others rate in this final determination, particularly because there is no other information on the record from which to determine the all-others rate.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[7] In making these findings, Commerce relied on facts otherwise available and, as discussed above and in the Issues and Decision Memorandum, because it finds that one or more respondents did not act to the best of their ability to respond to Commerce's requests for information, Commerce drew an adverse inference where appropriate in selecting from among the facts otherwise available.[8] For a full description of the methodology underlying our final

[1] *See Vertical Metal File Cabinets from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination,* 84 FR 37622 (August 1, 2019) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Vertical Metal File Cabinets from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Petitioner's Letter, ''Vertical Metal File Cabinets from the People's Republic of China: Petitioner's Case Brief,'' dated September 20, 2019.

[4] *See* Memorandum, ''Countervailing Duty Investigation of File Cabinets from the People's Republic of China: Delivery of Quantity and Value Questionnaire to Exporters/Producers,'' dated July 5, 2019.

[5] *See Vertical Metal File Cabinets from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 84 FR 24089 (May 24, 2019) (*Initiation Notice*) and accompanying Initiation Checklist; and Preliminary Decision Memorandum at 13–37.

[6] *See* Initiation Checklist. For an analysis of this information, *see* Preliminary Decision Memorandum at 13–41.

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[8] *See* section 776(a)–(b) of the Act.

[9] *See* Appendix III: List of Companies Receiving AFA Rate.

[10] *See* Appendix IV: List of Companies Receiving All-Others Rate.

determination, *see* the Issues and Decision Memorandum.

Final Determination

In accordance with section 705(c)(1)(B)(i)(I) of the Act, we established estimated countervailable subsidy rates, as follows:

Company	Subsidy rate (percent)
Non-Responsive Companies [9]	271.79
All Others [10]	271.79

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with the final determination within five days of its public announcement, or if there is no public announcement, within five days of the date of this notice, in accordance with 19 CFR 351.224(b). However, because Commerce continued to apply total AFA rates in the calculation of the benefit for the non-responsive companies based on rates calculated in prior proceedings, there are no calculations to disclose.

Continuation of Suspension of Liquidation

In accordance with sections 703(d) of the Act, Commerce instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of all appropriate entries of file cabinets from China, as described in Appendix I of this notice, which were entered or withdrawn from warehouse, for consumption, on or after August 1, 2019, the date of publication of the *Preliminary Determination* in the **Federal Register**, for all producers and exporters of merchandise under consideration. In accordance with section 705(c)(1)(B)(ii) of the Act, we are directing CBP to continue to suspend liquidation of all imports of subject merchandise from China that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The suspension of liquidation instructions will remain in effect until further notice. We are also directing CBP to collect cash deposits of estimated countervailing duties at the rates identified above.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

International Trade Commission Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our final affirmative determination that countervailable subsidies are being provided to producers and exporters of file cabinets from China. Because the final determination in this proceeding is affirmative, in accordance with section 705(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, or sales (or the likelihood of sales) for importation of file cabinets from China before the later of 120 days after the date of this preliminary determination or 45 days after the final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated, and all cash deposits will be refunded. If the ITC determines that such injury does exist, Commerce will issue a CVD order directing CBP to assess, upon further instruction by Commerce, countervailing 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.

Administrative Protective Orders

This notice serves as the only reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the 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.

Notification to Interested Parties

This determination is issued and published in accordance with sections 705(d) and 777(i) of the Act and 19 CFR 351.210(c).

Dated: October 7, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The scope of this investigation covers freestanding vertical metal file cabinets containing two or more extendable file storage elements and having an actual width of 25 inches or less.

The subject vertical metal file cabinets have bodies made of carbon and/or alloy steel and or other metals, regardless of whether painted, powder coated, or galvanized or otherwise coated for corrosion protection or aesthetic appearance. The subject vertical metal file cabinets must have two or more extendable elements for file storage (*e.g.,* file drawers) of a height that permits hanging files of either letter (8.5″ x 11″) or legal (8.5″ x 14″) sized documents.

An ''extendable element'' is defined as a movable load-bearing storage component including, but not limited to, drawers and filing frames. Extendable elements typically have suspension systems, consisting of glide blocks or ball bearing glides, to facilitate opening and closing.

The subject vertical metal file cabinets typically come in models with two, three, four, or five-file drawers. The inclusion of one or more additional non-file-sized extendable storage elements, not sized for storage files (*e.g.,* box or pencil drawers), does not remove an otherwise in-scope product from the scope as long as the combined height of the non-file-sized extendable storage elements does not exceed six inches. The inclusion of an integrated storage area that is not extendable (*e.g.,* a cubby) and has an actual height of six inches or less, also does not remove a subject vertical metal file cabinet from the scope. Accessories packaged with a subject vertical file cabinet, such as separate printer stands or shelf kits that sit on top of the in-scope vertical file cabinet are not considered integrated storage.

''Freestanding'' means the unit has a solid top and does not have an open top or a top with holes punched in it that would permit the unit to be attached to, hung from, or otherwise used to support a desktop or other work surface. The ability to anchor a vertical file cabinet to a wall for stability or to prevent it from tipping over does not exclude the unit from the scope.

The addition of mobility elements such as casters, wheels, or a dolly does not remove the product from the scope. Packaging a subject vertical metal file cabinet with other accessories, including, but not limited to, locks, leveling glides, caster kits, drawer accessories (*e.g.,* including but not limited to follower wires, follower blocks, file compressors, hanger rails, pencil trays, and hanging file folders), printer stand, shelf kit and magnetic hooks, also does not remove the product from the scope. Vertical metal file cabinets are also in scope whether they are imported assembled or unassembled with all essential parts and components included.

Excluded from the scope are lateral metal file cabinets. Lateral metal file cabinets have a width that is greater than the body depth, and have a body with an actual width that is more than 25 inches wide.

Also excluded from the scope are pedestal file cabinets. Pedestal file cabinets are metal file cabinets with body depths that are greater than or equal to their width, are under 31 inches in actual height, and have the following characteristics: (1) An open top or other the means for the cabinet to be attached

to or hung from a desktop or other work surface such as holes punched in the top (*i.e.,* not freestanding); or (2) freestanding file cabinets that have all of the following: (a) At least a 90 percent drawer extension for all extendable file storage elements; (b) a central locking system; (c) a minimum weight density of 9.5 lbs./cubic foot; and (d) casters or leveling glides.

''Percentage drawer extension'' is defined as the drawer travel distance divided by the inside depth dimension of the drawer. Inside depth of drawer is measured from the inside of the drawer face to the inside face of the drawer back. Drawer extension is the distance the drawer travels from the closed position to the maximum travel position which is limited by the out stops. In situations where drawers do not include an outstop, the drawer is extended until the drawer back is 3½ inches from the closed position of inside face of the drawer front. The ''weight density'' is calculated by dividing the cabinet's actual weight by its volume in cubic feet (the multiple of the product's actual width, depth, and height). A ''central locking system'' locks all drawers in a unit.

Also excluded from the scope are fire proof or fire-resistant file cabinets that meet Underwriters Laboratories (UL) fire protection standard 72, class 350, which covers the test procedures applicable to fire-resistant equipment intended to protect paper records.

The merchandise subject to the investigation is classified under Harmonized Tariff Schedule of the United States (HTSUS) subheading 9403.10.0020. The subject merchandise may also enter under HTSUS subheadings 9403.10.0040, 9403.20.0080, and 9403.20.0090. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Period of Investigation
IV. Scope of Investigation
V. Use of Facts Otherwise Available and Adverse Inferences
VI. Discussion of the Issues
VII. Recommendation

Appendix III

List of Non-Responsive Companies Receiving AFA Rate

1. Best Beauty Furniture Co., Ltd.
2. Chung Wah Steel Furniture Factory
3. Concept Furniture (Anhui) Co., Ltd.
4. Dong Guan Shing Fai Furniture
5. Dongguan Zhisheng Furniture Co., Ltd.
6. Feel Life Co., Ltd.
7. Fujian lvyer Industrial Co., Ltd.
8. Fuzhou Nu Deco Crafts Co., Ltd.
9. Fuzhou Yibang Furniture Co., Ltd.
10. Gold Future Furnishing Co., Ltd.
11. Guangdong Hongye Furniture
12. Guangxi Gicon Office Furniture Co., Ltd.
13. Guangzhou City Yunrui Imp.
14. Hangzhou Zongda Co., Ltd.
15. Heze Huayi Chemical Co., Ltd.
16. Highbright Enterprise Ltd.
17. Homestar Corp.
18. Honghui Wooden Crafts Co., Ltd.
19. Huabao Steel Appliance Co., Ltd.
20. I.D. International Inc.
21. Jiangmen Kinwai International
22. Jiaxing Haihong Electromechanical Technology Co., Ltd.
23. Long Sheng Office Furniture
24. Louyong Hua Zhi Jie Office Furniture Co., Ltd.
25. Luoyang Hua Wei Office Furniture Co., Ltd.
26. Luoyang Huadu Imp. Exp. Co., Ltd.
27. Luoyang Mas Younger Office Furniture Co., Ltd.
28. Luoyang Shidiu Import & Export Co., Ltd.
29. Luoyang Zhenhai Furniture Co., Ltd.
30. Ningbo Sunburst International Trading Co., Ltd.
31. Ri Time Group Inc. (Szx)
32. Shenzhen Heng Li de Industry Co., Ltd.
33. Shenzhen Zhijuan (Zhiyuan) Technology Co., Ltd.
34. Shiny Way Furniture Co., Ltd.
35. South Metal Furniture Factory
36. Suzhou Jie Quan (Jinyuan) Trading Co., Ltd.
37. T. H. I. Group (Shanghai) Ltd.
38. Tianjin First Wood Co., Ltd.
39. UenJoy (Tianjin) Technology Co., Ltd.
40. Xiamen Extreme Creations
41. Xinhui Second Light Machinery Factory Co., Ltd
42. Yahee Technologies
43. Zhe Jiang Jiayang Imp. & Exp. Co., Ltd.
44. Zhejiang Ue Furniture Co., Ltd.
45. Zhong Shan Yue Qin Imp. & Exp.
46. Zhongshan Fmarts Furniture Co., Ltd

Appendix IV

List of Companies Receiving All-Others Rate

The companies receiving the all-others rate include:

1. Guangzhou Perfect Office Furniture
2. Guangzhou Textiles Holdings Limited
3. Huisen Furniture (Longnan) Co., Ltd.
4. Invention Global Ltd.
5. Jiangxi Yuanjin Science & Technology Group Co., Ltd.
6. Jpc Co., Ltd. (HK)
7. Leder Lighting Co., Ltd.
8. Luoyang Cuide Imp. & Exp.
9. Ningbo Haishu Spark Imp. & Exp. Co., Ltd.
10. Ningbo Haitian International Co.
11. Qingdao Liansheng
12. Shanxi Ktl Agricultural Technology Co., Ltd.
13. Shanxi Sijian Group Co., Ltd.
14. Shenzhen Zhilai Sci and Tech Co., Ltd.
15. Top Perfect Ltd.
16. Zhengzhou Puhui Trading Co., Ltd.

[FR Doc. 2019–23338 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–978]

High Pressure Steel Cylinders From the People's Republic of China: Rescission of Countervailing Duty Administrative Review: 2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on certain high pressure steel cylinders (steel cylinders) from the People's Republic of China (China) for the period of review (POR) January 1, 2018 through December 31, 2018, based on the timely withdrawal of the requests for review.

DATES: Applicable October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Dusten Hom, 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) 482–5075.

SUPPLEMENTARY INFORMATION:

Background

On June 3, 2019, Commerce published a notice of opportunity to request an administrative review of the CVD order on steel cylinders from China for the POR of January 1, 2018, through December 31, 2018.[1] Commerce received a timely-filed request from Norris Cylinder Company (Norris) for an administrative review of Beijing Tianhai Industry Co., Ltd. (BTIC), Tianjin Tianhai High Pressure Container Co., Ltd. (Tianjin Tianhai), and Langfang Tianhai High Pressure Container Co., Ltd. (Langfang Tianhai) and a request from BTIC for a review of itself, in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b).[2]

On July 29, 2019, pursuant to these requests and in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice initiating an administrative review of the countervailing duty order

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 84 FR 25521 (June 3, 2019).

[2] *See* letter from Norris, ''High Pressure Steel Cylinders from the People's Republic of China; Request for Administrative Review,'' dated June 24, 2019, and BTIC, ''Request for the Seventh Administrative Review of the Countervailing Duty Order on High Pressure Steel Cylinders from the People's Republic of China, C–570–978 (POR: 01/01/18–12/31/18),'' dated June 27, 2019.

on steel cylinders from China with respect to BTIC, Tianjin Tianhai, and Langfang Tianhai.[3] On October 1, 2019, Norris and BTIC withdrew their requests for an administrative review.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraws the request within 90 days of the publication date of the notice of initiation of the requested review. Norris withdrew its request for review of BTIC, Langfang Tianhai High Pressure Container, and Tianjin Tianhai High Pressure Container, and BTIC withdrew its request for review of itself. Both parties withdrew their requests within 90 days of the publication date of the notice of initiation. No other parties requested an administrative review of the order. Therefore, in accordance with 19 CFR 351.213(d)(1), we are rescinding this review in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries of HPSC from China. Countervailing duties shall be assessed at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to all 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. Timely written notification of the return/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 violation which is subject to sanction.

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: October 21, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–23336 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DS–P

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 36572 (July 29, 2019).

[4] *See* letter from Norris, ''High Pressure Steel Cylinders from the People's Republic of China; Withdrawal of Request for Administrative Review,'' and BTIC, ''Withdrawal of Review Request in the Seventh Administrative Review of Countervailing Duty Order on High Pressure Steel Cylinders from the People's Republic of China,'' dated October 1, 2019.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–110]

Vertical Metal File Cabinets From the People's Republic of China: Final 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 vertical metal file cabinets (file cabinets) 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).

DATES: Applicable October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Kathryn Wallace, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6251.

SUPPLEMENTARY INFORMATION:

Background

On August 1, 2019, Commerce published its *Preliminary Determination* of sales at LTFV of file cabinets from China and gave parties an opportunity to comment.[1] Commerce received no comments or requests for a hearing. As there are no changes from, or comments upon, the *Preliminary Determination,* Commerce finds that there is no reason to modify its analysis. Accordingly, no decision memorandum accompanies this **Federal Register** notice. For further details of the issues addressed in this proceeding, *see* the *Preliminary Determination.*[2]

[1] *See Vertical Metal File Cabinets from the Republic of China: Preliminary Affirmative Determination of Sales at Less Than Fair Value,* 84 FR 37618 (August 1, 2019) (*Preliminary Determination*), and accompanying Preliminary Decision Memorandum.

[2] *See Preliminary Determination,* 84 FR at 37618.

Period of Investigation

The period of investigation (POI) is October 1, 2017 through March 31, 2018.

Scope of the Investigation

The merchandise covered by this investigation is file cabinets from China. For a complete discussion of the scope of this investigation, *see* the Appendix to this notice.

Separate Rates

As no company subject to this investigation submitted an application for separate rate status, Commerce preliminarily determined that none of the companies subject to this investigation demonstrated eligibility for separate rate status and were thus found to be part of the China-wide entity.[3] In this final determination, we continue to treat all 62 exporters or producers subject to this investigation as part of the China-wide entity.[4]

China-Wide Entity

As explained in the *Preliminary Determination,* Commerce did not receive timely responses to its quantity and value (Q&V) questionnaire from exporters and/or producers of subject merchandise that were named in the petition and to which Commerce issued Q&V questionnaires.[5] As noted above, these non-responsive companies also did not demonstrate separate rate eligibility, and accordingly, were determined to be a part of the China-wide entity. Furthermore, as explained in the *Preliminary Determination,* the China-wide entity failed to provide necessary information, withheld information requested by Commerce, failed to provide information in a timely manner, and significantly impeded this proceeding by not submitting the requested information. Moreover, the China-wide entity was found to be non-cooperative.[6] Thus, we continue to find that the use of adverse facts available (AFA) pursuant to section 776(a)–(b) of the Act is appropriate, and we are continuing to base the China-wide entity's rate on AFA.

China-Wide Rate

In selecting the AFA rate for the China-wide entity, Commerce's practice is to select a rate that is sufficiently adverse to ensure that the uncooperative party does not obtain a more favorable result by failing to cooperate than if it

[3] *Id.*

[4] *Id.*

[5] *See* Preliminary Decision Memorandum at 6.

[6] *Id.* at 6–7.

had fully cooperated.[7] Specifically, it is Commerce's practice to select, as an AFA rate, the higher of: (a) The highest dumping margin alleged in the petition; or (b) the highest calculated dumping margin of any respondent in the investigation.[8] As AFA, Commerce has continued to assign to the China-wide entity the highest petition rate, 198.5 percent.[9]

Final Determination

Commerce determines that the following weighted-average dumping margins exist for the period October 1, 2018 through March 31, 2019:

Producer/exporter	Estimated weighted-average dumping margin (percent)	Estimated weighted-average dumping margin adjusted for export subsidy offset (percent)
China-Wide Entity	198.5	160.77

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with a preliminary determination within five days of its public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). However, because Commerce applied total AFA to the China-wide entity in this investigation in accordance with section 776 of the Act, and the applied AFA rate is based solely on the petition, there are no calculations to disclose.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, we will instruct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all appropriate entries of file cabinets from China, as described in the appendix to this notice, which were entered, or withdrawn from warehouse, for consumption on or after August 1, 2019, the date of publication of the *Preliminary Determination* of this investigation in the **Federal Register**. Further, Commerce will instruct CBP to require a cash deposit equal to the estimated amount by which the normal value exceeds the U.S. price as shown above.

To determine the cash deposit rate, Commerce normally adjusts the estimated weighted-average dumping margin by the amount of domestic subsidy pass-through and export subsidies determined in a companion CVD proceeding when CVD provisional measures are in effect. Accordingly, where Commerce makes an affirmative determination for domestic subsidy pass-through or export subsidies, Commerce offsets the calculated estimated weighted-average dumping margin by the appropriate rate(s). Commerce continues to find no domestic subsidy-pass through and to adjust for export subsidies, as explained in the *Preliminary Determination*.[10]

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), Commerce will instruct CBP to require a cash deposit equal to the weighted-average amount by which NV exceeds U.S. price as follows: (1) For all combinations of exporters/producers of merchandise under consideration that have not received their own separate rate, the cash-deposit rate will be the cash deposit rate established for the China-wide entity; and (2) for all non-Chinese exporters of the merchandise under consideration which have not received their own separate rate above, the cash-deposit rate will be the cash deposit rate applicable to the Chinese exporter/producer combination that supplied that non-Chinese exporter. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission (ITC) Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of the 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, or sales (or the likelihood of sales) for importation of file cabinets from China before the later of 120 days after our preliminary determination or 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated, and all cash deposits will be refunded. 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 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 Orders

This notice serves as the only reminder to parties subject to an 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 notification of the return or 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 violation subject to sanction.

Notification to Interested Parties

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).

[7] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Purified Carboxymethyl cellulose from Finland,* 69 FR 77216, 77219 (December 27, 2004), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Purified Carboxymethyl Cellulose from Finland,* 70 FR 28279, 28279 (May 17, 2005).

[8] *See, e.g., Certain Stilbenic Optical Brightening Agents from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 77 FR 17436, 17438 (March 26, 2012); *Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Flat-Rolled Carbon Quality Steel Products from the People's Republic of China,* 65 FR 34660 (May 31, 2000), and accompanying Issues and Decision Memorandum.

[9] *See Preliminary Determination* at 84 FR 37618.

[10] *See* Preliminary Decision Memorandum at 9–10.

Dated: October 7, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Investigation

The scope of this investigation covers freestanding vertical metal file cabinets containing two or more extendable file storage elements and having an actual width of 25 inches or less.

The subject vertical metal file cabinets have bodies made of carbon and/or alloy steel and or other metals, regardless of whether painted, powder coated, or galvanized or otherwise coated for corrosion protection or aesthetic appearance. The subject vertical metal file cabinets must have two or more extendable elements for file storage (*e.g.,* file drawers) of a height that permits hanging files of either letter (8.5″ x 11″) or legal (8.5″ x 14″) sized documents.

An ''extendable element'' is defined as a movable load-bearing storage component including, but not limited to, drawers and filing frames. Extendable elements typically have suspension systems, consisting of glide blocks or ball bearing glides, to facilitate opening and closing.

The subject vertical metal file cabinets typically come in models with two, three, four, or five-file drawers. The inclusion of one or more additional non-file-sized extendable storage elements, not sized for storage files (*e.g.,* box or pencil drawers), does not remove an otherwise in-scope product from the scope as long as the combined height of the non-file-sized extendable storage elements does not exceed six inches. The inclusion of an integrated storage area that is not extendable (*e.g.,* a cubby) and has an actual height of six inches or less, also does not remove a subject vertical metal file cabinet from the scope. Accessories packaged with a subject vertical file cabinet, such as separate printer stands or shelf kits that sit on top of the in-scope vertical file cabinet are not considered integrated storage.

''Freestanding'' means the unit has a solid top and does not have an open top or a top with holes punched in it that would permit the unit to be attached to, hung from, or otherwise used to support a desktop or other work surface. The ability to anchor a vertical file cabinet to a wall for stability or to prevent it from tipping over does not exclude the unit from the scope.

The addition of mobility elements such as casters, wheels, or a dolly does not remove the product from the scope. Packaging a subject vertical metal file cabinet with other accessories, including, but not limited to, locks, leveling glides, caster kits, drawer accessories (*e.g.,* including but not limited to follower wires, follower blocks, file compressors, hanger rails, pencil trays, and hanging file folders), printer stand, shelf kit and magnetic hooks, also does not remove the product from the scope. Vertical metal file cabinets are also in scope whether they are imported assembled or unassembled with all essential parts and components included.

Excluded from the scope are lateral metal file cabinets. Lateral metal file cabinets have a width that is greater than the body depth, and have a body with an actual width that is more than 25 inches wide.

Also excluded from the scope are pedestal file cabinets. Pedestal file cabinets are metal file cabinets with body depths that are greater than or equal to their width, are under 31 inches in actual height, and have the following characteristics: (1) An open top or other the means for the cabinet to be attached to or hung from a desktop or other work surface such as holes punched in the top (*i.e.,* not freestanding); or (2) freestanding file cabinets that have all of the following: (a) At least a 90 percent drawer extension for all extendable file storage elements; (b) a central locking system; (c) a minimum weight density of 9.5 lbs./cubic foot; and (d) casters or leveling glides.

''Percentage drawer extension'' is defined.as the drawer travel distance divided by the inside depth dimension of the drawer. Inside depth of drawer is measured from the inside of the drawer face to the inside face of the drawer back. Drawer extension is the distance the drawer travels from the closed position to the maximum travel position which is limited by the out stops. In situations where drawers do not include an outstop, the drawer is extended until the drawer back is 3-l/2 inches from the closed position of inside face of the drawer front. The ''weight density'' is calculated by dividing the cabinet's actual weight by its volume in cubic feet (the multiple of the product's actual width, depth, and height). A ''central locking system'' locks all drawers in a unit.

Also excluded from the scope are fire proof or fire-resistant file cabinets that meet Underwriters Laboratories (UL) fire protection standard 72, class 350, which covers the test procedures applicable to fire-resistant equipment intended to protect paper records.

The merchandise subject to the investigation is classified under Harmonized Tariff Schedule of the United States (HTSUS) subheading 9403.10.0020. The subject merchandise may also enter under HTSUS subheadings 9403.10.0040, 9403.20.0080, and 9403.20.0090. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

[FR Doc. 2019–23337 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–851]

Certain Small Diameter Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Under 4½ Inches) From Japan: Rescission of Antidumping Duty Administrative Review: 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the antidumping duty (AD) order on certain small diameter carbon and alloy seamless standard, line, and pressure pipe (under 4½ inches) from Japan for the period of review (POR) June 1, 2018 through May 31, 2019, based on the timely withdrawal of the request for review.

DATES: Applicable October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Dusten Hom, AD/CVD Operations, Office 1, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5075.

SUPPLEMENTARY INFORMATION:

Background

On June 3, 2019, Commerce published a notice of opportunity to request an administrative review of the antidumping duty order on certain small diameter carbon and alloy seamless standard, line, and pressure pipe (under 4½ inches) from Japan for the POR of June 1, 2018 through May 31, 2019.[1] United States Steel Corporation (U.S. Steel) timely filed requests for an administrative review of Denka Company Limited (Denka), Ebara Corporation (Ebara), JFE Steel Corporation (JFE Steel), Kaneka Corporation (Kaneka), Kawasaki Steel Corporation (Kawasaki Steel), Maruichi Kohan Limited (Maruichi), Metal One Tubular Products Incorporated (Metal One), Nippon Steel & Sumitomo Metal Corporation (N&S), Nippon Steel Corporation (Nippon Steel), NKK Tubes (NKK), Okaya & Company Limited (Okaya), Sumitomo Corporation (Sumitomo Corp.), Sumitomo Metal Industries Limited (Sumitomo Metal), Taiheiyo Cement Corporation (Taiheiyo), Vallourec & Sumitomo Tubos do Brasil Limitada (V&C), Vallourec Solucoes Tubulares do Brasil (Vallourec Solucoes), and Yamashin Industry Company (Yamashin), in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b).[2]

On July 29, 2019, pursuant to these requests, and in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice initiating an

[1] *See Antidumping or Countervailing Duty Order. Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 84 FR 25521 (June 3, 2019).

[2] *See* letter from U.S. Steel, ''Carbon and Alloy Seamless Standard line, and Pressure Pipe (Under 4½ Inches) from Japan: Request for Administrative Review of Antidumping Duty Order,'' dated June 28, 2019.

administrative review of the antidumping duty order on small diameter carbon and alloy seamless standard, line, and pressure pipe (under 4½ inches) from Japan with respect to Denka, Ebara, JFE Steel, Kaneka, Kawasaki Steel, Maruichi, Metal One, N&S, Nippon Steel, NKK, Okaya, Sumitomo Corp., Sumitomo Metal, Taiheiyo, V&C, Vallourec Solucoes, and Yamashin.[3] On September 4, 2019, U.S. Steel withdrew its request for an administrative review with respect to all of the companies for which it had requested a review.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraws the request within 90 days of the publication date of the notice of initiation of the requested review. U.S. Steel withdrew its request for review of Denka, Ebara, JFE Steel, Kaneka, Kawasaki Steel, Maruichi, Metal One, N&S, Nippon Steel, NKK, Okaya, Sumitomo Corp., Sumitomo Metal, Taiheiyo, V&C, Vallourec Solucoes, and Yamashin. U.S. Steel withdrew its request within 90 days of the publication date of the notice of initiation. No other parties requested an administrative review of the order. Therefore, in accordance with 19 CFR 351.213(d)(1), we are rescinding this review in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries of small diameter carbon and alloy seamless standard, line, and pressure pipe (under 4½ inches) from Japan. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 36572 (July 29, 2019).

[4] *See* letter from U.S. Steel, ''Carbon and Alloy Seamless Standard, Line, and Pressure Pipe (Under 4.5 Inches) from Japan: Withdrawal of Request for Administrative Review of Antidumping Duty Order,'' dated September 24, 2019.

Notification to Importers

This notice serves as a reminder to importers of their responsibility under 19 CFR 351.42(f)(2) to file a certificate regarding the reimbursement of AD duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of AD duties occurred and the subsequent assessment of doubled AD duties.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to all 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. Timely written notification of the return/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 violation which is subject to sanction.

This notice is issues and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: October 21, 2019.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2019–23339 Filed 10–24–19; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–820]

Fresh Tomatoes From Mexico: Final 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 fresh tomatoes from Mexico are being, or are likely to be, sold in the United States at less than fair value (LTFV). The final estimated weighted-average dumping margins are listed below in the ''Final Determination'' section of this notice.

DATES: Applicable October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun or Hermes Pinilla, 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) 482–5760 and (202) 482–3477, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 7, 2019, Commerce terminated the *2013 Suspension Agreement*[1] on fresh tomatoes from Mexico and continued the LTFV investigation of fresh tomatoes from Mexico.[2] The original period of investigation was March 1, 1995 through February 29, 1996. Due to the unusual procedural posture of this proceeding, in which we terminated a suspension agreement and continued an investigation that covers a period of investigation that dates back more than 23 years, Commerce determined to request information corresponding to the most recent four full quarters, *i.e.,* April 1, 2018 through March 31, 2019.[3] Based on the unusual procedural posture, we also found it appropriate to reconsider respondent selection.[4] On May 24, 2019, we selected Bioparques de Occidente, S.A. de C.V. (Bioparques), Ceuta Produce, S.A. de C.V. (Ceuta), and Negocio Agricola San Enrique, S.A. de C.V. (San Enrique) for individual examination in this continued investigation.[5] On July 23, 2019, Commerce issued the post-preliminary decision based on the information requested from, and provided by, Bioparques, Ceuta, and San Enrique.[6] Commerce received case and rebuttal briefs on August 30, 2019, and September 4, 2019, respectively.[7]

[1] *See Fresh Tomatoes From Mexico: Suspension of Antidumping Investigation,* 78 FR 14967 (March 8, 2013) (*2013 Suspension Agreement*).

[2] *See Fresh Tomatoes From Mexico: Termination of Suspension Agreement, Rescission of Administrative Review, and Continuation of the Antidumping Duty Investigation,* 84 FR 20858 (May 13, 2019) (*Continuation Notice*).

[3] *Id.,* 84 FR at 20860–61.

[4] *Id.,* 84 FR at 20861.

[5] *See* Memorandum, ''Less-Than-Fair-Value Investigation of Fresh Tomatoes from Mexico: Respondent Selection,'' dated May 24, 2019.

[6] *See* Memorandum, ''Post-Preliminary Decision Memorandum in the Less-Than-Fair-Value Investigation of Fresh Tomatoes from Mexico,'' dated July 23, 2019 (Post-Preliminary Decision).

[7] *See* Florida Tomato Exchange's Case Brief dated August 30, 2019, the Mexican Respondents' Case Brief dated August 30, 2019, Red Sun Farms' Redacted Case Brief dated September 11, 2019, Florida Tomato Exchange's Rebuttal Brief dated September 4, 2019, and the Mexican Respondents' Rebuttal Brief dated September 4, 2019. Red Sun Farms submitted its original case brief on August 30, 2019, which we rejected on September 9, 2019, for containing untimely filed new factual information. *See* Commerce's Letter to Red Sun Farms dated September 9, 2019. Red Sun Farms submitted its partially redacted case brief on September 11, 2019.

Continuation of Investigation

On September 19, 2019, Commerce and representatives of the signatory producers/exporters accounting for substantially all imports of fresh tomatoes from Mexico signed an agreement to suspend this investigation (the 2019 Agreement).[8] On October 11, 2019, the Florida Tomato Exchange, a member of the U.S. petitioning industry, timely requested that Commerce continue this investigation.[9] On October 15, 2019, Red Sun Farms also timely requested that Commerce continue this investigation.[10] Commerce has continued and completed this investigation in accordance with section 734(g) of the Tariff Act of 1930, as amended (the Act).

Scope of the Investigation

For a complete description of the scope of this investigation, *see* the ''Scope of the Investigation'' in Appendix I of this notice.

Scope Comments

In the post-preliminary decision, we addressed comments concerning the scope of this investigation.[11] No party filed comments in its case brief concerning the scope of the investigation. Therefore, we have made no changes to the scope of the investigation in the final determination.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice.[12] A list of the issues raised is attached to this notice as Appendix II. 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 *https://access.trade.gov* and it is available to all parties in the Central Records Unit, room B–8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version are identical in content.

Verification

As provided in section 782(i) of the Act, in August 2019, Commerce verified the sales and cost data reported by Bioparques, Ceuta, and San Enrique. 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 Post-Preliminary Analysis

Based on the respondents' supplemental responses and revised sales and cost databases, our findings at verification, and our analysis of the comments received, we made certain changes to the margin calculations in the post-preliminary decision. For a discussion of these changes, *see* the Issues and Decision Memorandum. We have also revised the all-others rate.

All-Others Rate

Section 735(c)(5)(A) of the Act provides that Commerce estimate the weighted-average dumping margin for all other producers or exporters not subject to individual examination equal to the weighted average of the estimated weighted-average dumping margins of the individually examined respondents, excluding any rates that are zero, *de minimis,* or based entirely on facts available pursuant to section 776 of the Act. For purposes of this final determination, we are assigning 20.91 percent as the all-others rate, which is based on the weighted average of the estimated dumping margins calculated for the three individually examined respondents whose margins are above *de minimis* in the continued investigation.[13]

Final Determination

Commerce determines that the final weighted-average dumping margins are as follows:

Producer/exporter	Weighted-average dumping margin (percent)
Bioparques de Occidente, S.A. de C.V./Agricola La Primavera, S.A. de C.V.[14]	30.48
Ceuta Produce, S.A. de C.V./Rancho La Memoria, S. de R.L. de C.V.[15]	3.91
Negocio Agricola San Enrique, S.A. de C.V	17.02
All Others	20.91

Disclosure

We intend to disclose the calculations performed to interested parties within five days of the public announcement of this final determination consistent with 19 CFR 353.20(e) (1996).

Suspension of Liquidation

As noted above, on September 19, 2019, Commerce and representatives of the signatory producers/exporters accounting for substantially all imports of fresh tomatoes from Mexico signed the 2019 Agreement. Consistent with section 734(h)(3) of the Act, the suspension of liquidation ordered following the May 7, 2019 continuation of the investigation remained in effect.[16] No interested party requested a review of the suspension of the investigation by the U.S. International Trade Commission (ITC) under section 734(h) of the Act. Therefore, in accordance with section 734(h)(3) of the Act, and because the 2019 Agreement remains in force, Commerce is instructing U.S. Customs and Border Protection to terminate the suspension of liquidation of all entries of fresh tomatoes from Mexico, entered, or withdrawn from warehouse, for consumption on or after May 7, 2019, and to liquidate the entries without regard to antidumping duties (*i.e.,* to refund any cash deposits and release any bonds for such entries).

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the ITC of the final affirmative determination of sales

[8] *See Fresh Tomatoes From Mexico: Suspension of Antidumping Duty Investigation,* 84 FR 49987 (September 24, 2019) (*2019 Suspension Agreement*).

[9] *See* Florida Tomato Exchange's Letter, ''Fresh Tomatoes from Mexico: Request to Continue Suspended Less Than Fair Value Investigation,'' dated October 11, 2019. Florida Tomato Exchange is a member of the petitioning group that filed the petition in this investigation. *See Initiation of Antidumping Duty Investigation: Fresh Tomatoes From Mexico,* 61 FR 18377 (April 25, 1996).

[10] *See* Red Sun Farms' Letter, ''Request to Continue Suspended Antidumping Duty Investigation,'' dated October 15, 2019.

[11] *See* Post-Preliminary Decision at 4–5.

[12] *See* Memorandum, ''Fresh Tomatoes from Mexico: Issues and Decision Memorandum for the Final Determination of Sales at the Less Than Fair Value,'' dated concurrently with this notice (Issues and Decision Memorandum).

[13] *See* Memorandum, ''Fresh Tomatoes from Mexico: Final All-Others Rate,'' dated concurrently with this notice.

[14] In this investigation we have determined that Bioparques de Occidente, S.A. de C.V. and Agricola La Primavera, S.A. de C.V. are affiliated and should be treated as a single entity. *See* Issues and Decision Memorandum at 4–6.

[15] In this investigation we have determined that Ceuta Produce, S.A. de C.V. and Rancho La Memoria, S. de R.L. de C.V. are affiliated and should be treated as a single entity. *See* Issues and Decision Memorandum at 4–6.

[16] *See 2019 Suspension Agreement,* 84 FR at 49989 (''The suspension of liquidation ordered following the May 7, 2019 continuation of the investigation shall continue to be in effect, subject to section 734(h)(3) of the Act.'').

at LTFV. Because the final determination in this investigation 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 fresh tomatoes from Mexico no later than 45 days after our final determination. If the ITC determines that material injury or threat of material injury does not exist, the 2019 Agreement will have no force or effect, and the investigation will be terminated.[17] If the ITC determines that material injury or threat of material injury does exist, the 2019 Agreement shall remain in force. Commerce will not issue an antidumping duty order so long as: (1) The 2019 Agreement remains in force; (2) the 2019 Agreement continues to meet the requirements of sections 734(c) and (d) of the Act; and (3) the parties to the 2019 Agreement carry out their obligations under the 2019 Agreement in accordance with its terms.[18]

Notification Regarding Administrative Protective Orders

This notice serves as a reminder to parties subject to an 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).[19] Timely notification of the return or 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 violation subject to sanction.

This determination and this notice are issued and published pursuant to sections 735(d) and 777(i)(1) of the Act.

Dated: October 21, 2019.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise subject to the investigation is all fresh or chilled tomatoes (fresh tomatoes) which have Mexico as their origin, except for those tomatoes which are for processing. For purposes of this suspended investigation, processing is defined to include preserving by any commercial process, such as canning, dehydrating, drying, or the addition of chemical substances, or converting the tomato product into juices, sauces, or purees. Fresh tomatoes that are imported for cutting up, not further processing (*e.g.,* tomatoes used in the preparation of fresh salsa or salad bars), are covered by the investigation.

Commercially grown tomatoes, both for the fresh market and for processing, are classified as Lycopersicon esculentum. Important commercial varieties of fresh tomatoes include common round, cherry, grape, plum, greenhouse, and pear tomatoes, all of which are covered by this investigation.

Tomatoes imported from Mexico covered by this investigation are classified under the following subheading of the Harmonized Tariff Schedule of the United States (HTSUS), according to the season of importation: 0702. Although the HTSUS numbers are provided for convenience and customs purposes, the written description of the scope of this investigation is disposition.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
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C. Bioparques
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VIII. Recommendation

[FR Doc. 2019–23341 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–DS–P

[17] *See* section 734(f)(3)(A) of the Act.

[18] *See* section 734(f)(3)(B) of the Act.

[19] *See Continuation Notice,* 84 FR at 20861 (stating that the procedures in 19 CFR 351.305 apply to this continued investigation).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR047

Marine Mammals; File No. 23169

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Red Rock Films, 625 Sligo Avenue, Silver Spring, MD 20910 (Responsible Party: Brian Armstrong), has applied in due form for a permit to conduct commercial or educational photography on marine mammals.

DATES: Written, telefaxed, or email comments must be received on or before November 25, 2019.

ADDRESSES: These documents are available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Shasta McClenahan or Amy Hapeman, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant proposes to film marine mammals in Antarctica to obtain footage for a National Geographic wildlife documentary focusing on social bonds and the complex communications that exist among cetaceans. Up to 150 humpback whales (*Megaptera novaeangliae*) and 100 killer whales (*Orcinus orca*) will be targeted over life

of permit for filming using vessels, underwater divers, or unmanned aircraft systems. Additional non-target marine mammals may be harassed and filmed if they are prey of killer whales or if opportunistically encountered. These non-target species include up to 10 minke whales (*Balaenoptera bonaerensis*) and 50 each of Antarctic fur seals (*Arctocephalus gazella*); crabeater seals (*Lobodon carcinophagus*), leopard seals (*Hydrurga leptonyx*), Ross seals (*Ommatophoca rossii*), southern elephant seals (*Mirounga leonina*), or Weddell seals (*Leptonychotes weddellii*) over the life of the permit. The permit would expire on February 28, 2021.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: October 22, 2019.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–23320 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR063

Marine Mammals; File No. 22678

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that NMFS' Marine Mammal Laboratory, Seattle Washington (Responsible Party: John Bengtson), has applied in due form for a permit to conduct research on pinnipeds.

DATES: Written, telefaxed, or email comments must be received on or before November 25, 2019.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 22678 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Sara Young or Shasta McClenahan, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The applicant proposes to conduct research on pinnipeds to meet the mandates of the MMPA and ESA by improving our understanding of west coast pinniped species through monitoring population abundance and trends, health, and behavior as mandated under the laws. The applicant requests the following: (1) Directed and incidental takes of the U.S. stock of California sea lions (*Zalophus californianus*); California, Oregon, Washington coast and Inland Washington stocks of Pacific harbor seals (*Phoca vitulina*); the California breeding stock of northern elephant seals (*Mirounga angustirostris*), and Mexico stock of Guadalupe fur seals (*Artocephalus townsendi*) and (2) incidental takes of the California stock of northern fur seals (*Callorhinus ursinus*) and eastern Pacific stock of Steller sea lions (*Eumetopias jubatus*). Up to 271,215 live California sea lions may be taken annually including 2,435 by capture for sampling, 80 by intentional mortality for humane purposes, and 268,700 by incidental disturbance. Research activities include: Aerial, vessel, ground, and observation surveys; capture for sampling of tissues, marking, and instrumentation; remote immobilization, biopsy and marking. Samples may be exported to domestic or foreign collaborators for analysis or archived. Up to 69,805 live Pacific harbor seals may be taken annually including 1,405 by capture for sampling and 68,400 by incidental disturbance. Up to 186,720 live northern elephant seals may be taken annually including 120 by capture for sampling and 186,600 by incidental disturbance. Up to 295 live Guadalupe fur seals may be taken annually including 130 by capture for sampling and 165 by incidental disturbance. Up to 20 live hybrid pinnipeds may be taken annually by capture for sampling. Up to 12 California sea lions, 6 harbor seals, 4 elephant seals, 3 Guadalupe fur seals, or 3 pinniped hybrids may be taken annually by unintentional mortality, with a maximum of 28 for all species over the duration of the permit. Up to 500 dead California sea lions, harbor seals, and elephant seals and 5 Guadalupe fur seals may be salvaged annually. The requested duration of the permit is 5 years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–23383 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR062

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice; determination on a Tribal Resource Management Plan.

SUMMARY: Notice is hereby given that NMFS has a determination on the Nez Perce Tribe's Tribal Resource Management Plan (TRMP) for fall Chinook and coho salmon in the Snake River Basin, pursuant to the protective regulations promulgated for Pacific salmon and steelhead under the Endangered Species Act (ESA). The TRMP specifies the implementation of fisheries targeting fall Chinook and coho salmon in the Snake River Basin and associated monitoring. NMFS took public comments on its recommended determination for how the plan addresses the criteria in § 223.203(b)(4) prior to making its final determination.

FOR FURTHER INFORMATION CONTACT: Charlene Hurst, at phone number: (503) 230–5409, or via email: *Charlene.n.hurst@noaa.gov.*

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notice

Chinook salmon (*Oncorhynchus tshawytscha*): Threatened, naturally produced and artificially propagated Snake River Spring/Summer, and Snake River Fall.

Steelhead (*O. mykiss*): Threatened, naturally produced and artificially propagated Snake River Basin.

Sockeye salmon (*O. nerka*): Endangered, naturally produced and artificially propagated Snake River.

Discussion of the Biological Analysis Underlying the Determination

The TRMP defines maximum impact rates/incidental mortality for listed species. Impacts to fall Chinook salmon are defined by a harvest schedule based on natural-origin fall Chinook salmon abundance measured at Lower Granite Dam. These maximum impact rates are part of a basin-wide framework with which all fishery managers have agreed to coordinate so that impacts do not exceed these maximums.

NMFS has analyzed the effects of the TRMP on ESA-listed salmon and steelhead species and has concluded that the TRMP would not appreciably reduce the likelihood of survival and recovery of ESA-listed species, while providing for the proposed tribal treaty harvest opportunities. Our determination depends upon implementation of all of the monitoring, evaluation, reporting tasks or assignments, and enforcement activities included in the TRMP. Reporting and inclusion of new information derived from research, monitoring, and evaluation activities described in the plan provide assurance that performance standards will be achieved in future seasons.

Summary of Comments Received on the Proposed Evaluation and Pending Determination

NMFS published notice of its Proposed Evaluation and Pending Determination (PEPD) on the plan for public review and comment on July 11, 2019 (84 FR 33062), as required by the Tribal 4(d) Rule. The PEPD was available for public review and comment for 30 days. No comments were received specific to the PEPD.

Authority

16 U.S.C. 1531–1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

Dated: October 21, 2019.

Angela Somma,

Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–23249 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR061

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice; availability of a fishery evaluation and management plan for public comment.

SUMMARY: Notice is hereby given that the Oregon Department of Fish and Wildlife (ODFW) has provided a Fishery Management and Evaluation Plan (FMEP) pursuant to the protective regulations promulgated for Pacific salmon and steelhead under the Endangered Species Act (ESA). The FMEP specifies the implementation of fisheries targeting Coho salmon and resident trout in Oregon waters of the Snake River Basin. This document serves to notify the public of the availability of the FMEP for comment prior to a decision by NMFS on whether to approve the proposed fisheries.

DATES: Comments must be received at the appropriate address (see **ADDRESSES**) no later than 5 p.m. Pacific time on November 25, 2019. Comments received after this date may not be accepted.

ADDRESSES: A website link to the FMEP is available under the Notices and Rules Section on our website: *https://www.fisheries.noaa.gov/region/west-coast.* Written comments on the application should be addressed to the NMFS Sustainable Fisheries Division, 1201 NE Lloyd Boulevard, Suite 1100, Portland, OR 97232. Comments may be submitted by email. The mailbox address for providing email comments is: *Snake.River.Salmon.Fisheries@noaa.gov.* Include in the subject line of the email comment the following identifier: Comments on Snake River Salmon Fisheries.

FOR FURTHER INFORMATION CONTACT: Charlene Hurst, at phone number: (503) 230–5409, or via email: *Charlene.n.hurst@noaa.gov.*

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notice

Chinook salmon (*Oncorhynchus tshawytscha*): Threatened, naturally produced and artificially propagated Snake River Spring/Summer, and Snake River Fall;

Steelhead (*O. mykiss*): Threatened, naturally produced and artificially propagated Snake River Basin;

Sockeye salmon (*O. nerka*): Endangered, naturally produced and artificially propagated Snake River.

The FMEP submitted by ODFW describes fisheries targeting adult hatchery-and natural-origin coho salmon and resident trout within Snake River Basin waters in Oregon and their boundary waters with Washington and Idaho. The FMEP was submitted to NMFS under limit 4 of the ESA 4(d) Rule for salmon and steelhead. These fisheries were designed to support recreational fishing opportunities while minimizing potential risks to ESA-listed species. The FMEP describes timing, location, harvest impact limits, licensing, gear requirements, and monitoring and evaluation. Prior to approving an FMEP, NMFS must publish notification announcing the availability of the FMEP for public review and comment.

Authority

16 U.S.C. 1531 1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

Dated: October 21, 2019.

Angela Somma,

Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2019–23246 Filed 10–24–19; 8:45 am]

BILLING CODE 3510–22–P

COMMISSION OF FINE ARTS

Notice of Meeting

The next meeting of the U.S. Commission of Fine Arts is scheduled for 21 November 2019, at 9:00 a.m. in the Commission offices at the National Building Museum, Suite 312, Judiciary Square, 401 F Street NW, Washington, DC 20001–2728. Items of discussion may include buildings, parks and memorials.

Draft agendas and additional information regarding the Commission are available on our website: *www.cfa.gov.* Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Thomas Luebke, Secretary, U.S. Commission of Fine Arts, at the above address; by emailing *cfastaff@cfa.gov;* or by calling 202–504–2200. Individuals requiring sign language interpretation for the hearing impaired should contact the Secretary at least 10 days before the meeting date.

Dated: October 18, 2019 in Washington, DC.

Thomas Luebke,

Secretary.

[FR Doc. 2019–23319 Filed 10–24–19; 8:45 am]

BILLING CODE 6330–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletions from the Procurement List.

SUMMARY: This action deletes a product and services from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Date deleted from the Procurement List:* November 24, 2019.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletions

On 9/13/2019 and 9/20/2019, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the product and services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product and services deleted from the Procurement List.

End of Certification

Accordingly, the following product and services are deleted from the Procurement List:

Products

NSN—Product Name: 3915–04–000–4368—Small Web Door Assembly
Contracting Activity: USPS, Topeka Purchasing Center, Topeka, KS

Services

Service Type: Bursting/Packaging Commemorative Stamps
Mandatory for: Department of the Interior: 1849 C Street NW, Washington, DC
Mandatory Source of Supply: Allied Community Services, Inc., Enfield, CT
Contracting Activity: OFFICE OF POLICY, MANAGEMENT, AND BUDGET, NBC ACQUISITION SERVICES DIVISION

Service Type: Janitorial/Custodial
Mandatory for: U.S. Army Reserve Center, Fort Hamilton, NY
Mandatory Source of Supply: Fedcap Rehabilitation Services, Inc., New York, NY
Contracting Activity: DEPT OF THE ARMY, W6QM MICC CTR–FT DIX (RC)

Service Type: Mailroom Operation
Mandatory for: Food and Drug Administration: 5630 Fishers Lane, Rockville, MD
Mandatory Source of Supply: Lt. Joseph P. Kennedy Institute, Washington, DC
Contracting Activity: FOOD AND DRUG ADMINISTRATION, DEPT OF HHS/FOOD AND DRUG ADMINISTRATION

Service Type: Laundry Service
Mandatory for: Immigration & Naturalization Service, 201 Varick Building, New York, NY
Contracting Activity: OFFICE OF POLICY, MANAGEMENT, AND BUDGET, NBC ACQUISITION SERVICES DIVISION

Service Type: Janitorial/Custodial
Mandatory for: VA Outpatient Clinic, Winston-Salem, NC
Mandatory Source of Supply: OE Enterprises, Inc., Hillsborough, NC
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 246–NETWORK CONTRACTING OFFICE 6

Service Type: Janitorial/Custodial
Mandatory for: Eugene Outpatient Clinic: Department of Veteran Affairs, Eugene, OR
Mandatory Source of Supply: Garten Services, Inc., Salem, OR
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, NAC

Service Type: Janitorial/Custodial
Mandatory for: West LA VA Community Base Clinic, Los Angeles, CA
Mandatory for: San Diego Vet Center: 2900 Sixth Avenue, San Diego, CA
Mandatory for: Veterans Outreach Center, Vista, CA
Mandatory Source of Supply: Job Options, Inc., San Diego, CA
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, NAC

Service Type: Janitorial/Custodial
Mandatory for: Veterans Affairs Medical Center: 7305 N. Military Trail, West Palm Beach, FL
Mandatory Source of Supply: Gulfstream Goodwill Industries, Inc., West Palm Beach, FL
Contracting Activity: VETERANS AFFAIRS, DEPARTMENT OF, 548P–WEST PALM PROSTHETICS

Patricia Briscoe,

Deputy Director, Business Operations (Pricing and Information Management).

[FR Doc. 2019–23294 Filed 10–24–19; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to the Procurement List.

SUMMARY: The Committee is proposing to add products to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: November 24, 2019.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

NSNs—Product Names:
6510–01–540–6484—Bandage, Compression ''H''
6510–01–549–0939—Dressing, Chest Seal, Bolin

Mandatory Source of Supply: Lighthouse Works, Orlando, FL

Contracting Activity: DEFENSE LOGISTICS AGENCY, DLA TROOP SUPPORT

Patricia Briscoe,

Deputy Director, Business Operations (Pricing and Information Management).

[FR Doc. 2019–23293 Filed 10–24–19; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, October 30, 2019; 1:30 p.m.

PLACE: Hearing Room 420, Bethesda Towers, 4330 East-West Highway, Bethesda, MD 20814.

STATUS: Commission Meeting—Open to the Public.

MATTER TO BE CONSIDERED: Briefing Matter: 3D Printing.

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, (301) 504–7479.

Dated: October 22, 2019.

Alberta E. Mills,

Secretary.

[FR Doc. 2019–23417 Filed 10–23–19; 11:15 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Wednesday, October 30, 2019; 10:00 a.m.*

PLACE: Hearing Room 420, Bethesda Towers, 4330 East-West Highway, Bethesda, MD 20814.

STATUS: Commission Meeting—Closed to the Public.

MATTER TO BE CONSIDERED: Compliance Matters: Staff will brief the Commission on the status of compliance matters.**

CONTACT PERSON FOR MORE INFORMATION: Alberta E. Mills, Secretary, Division of the Secretariat, Office of the General Counsel, U.S. Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814, (301) 504–7479.

Dated: October 22, 2019.

Alberta E. Mills,

Secretary.

[FR Doc. 2019–23418 Filed 10–23–19; 11:15 am]

BILLING CODE 6355–01–P

* The Commission unanimously determined by recorded vote that Agency business requires calling the meeting without seven calendar days advance public notice.

** The meeting notice is an update for a canceled meeting that was scheduled for October 16, 2019 at 1:30 p.m.

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2019–OS–0098]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment. DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by November 25, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Application for Priority Rating for Production or Construction Equipment; DD Form 691; OMB Control Number 0704–0055.

Type of Request: Extension.

Number of Respondents: 610.

Responses per Respondent: 1.

Annual Responses: 610.

Average Burden per Response: 1 hour.

Annual Burden Hours: 610.

Needs and Uses: Executive Order 12919 delegates to DoD authority to require certain contracts and orders relating to approved Defense Programs to be accepted and performed on a preferential basis. This program helps contractors acquire industrial equipment in a timely manner, thereby facilitating development and support of weapons systems and other important Defense Programs.

Affected Public: Business or other For-Profit; Not-for-Profit Institutions.

Frequency: On Occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: October 21, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2019–23245 Filed 10–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2019–OS–0099]

Submission for OMB Review; Comment Request

AGENCY: Defense Logistics Agency, DoD.

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by November 25, 2019.

ADDRESSES: Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer, Docket ID number, and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: ASSIST Database; OMB Control Number 0704–0188.

Type of Request: Extension.

Number of Respondents: 1,040.

Responses per Respondent: 432.

Annual Responses: 449,280.

Average Burden per Response: 66 hours.

Annual Burden Hours: 29,652,480.

Needs and Uses: The Data Item Descriptions in the ASSIST database, formerly the Acquisition Management Systems and Data Requirements Control List (AMSDL), contain data requirements used in Department of Defense (DoD) contracts. The information collected will be used by DoD personnel and other DoD contractors to support the design, test, manufacture, training, operation, and maintenance of procured items, including weapons systems critical to the national defense.

Affected Public: Business or other For-Profit.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: October 21, 2019.

Aaron T. Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2019–23266 Filed 10–24–19; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Notice of Orders Issued Under Section 3 of the Natural Gas Act During September 2019

	FE Docket Nos.
GABZA INTERNATIONAL GAS INC.)	19–93–LNG
TIDAL ENERGY MARKETING (U.S.) L.L.C	19–88–NG
TRANSALTA ENERGY MARKETING, (U.S.) INC	19–82–NG
PENTAGON ENERGY, LLC	19–97–CNG
CENOVUS ENERGY MARKETING LIMITED	19–94–NG
SAN DIEGO GAS & ELECTRIC COMPANY	19–98–NG
JUST ENERGY NEW YORK CORP	19–96–NG
VALENCE NATURAL GAS SOLUTIONS LLC	19–70–CNG
EDF TRADING NORTH AMERICA, LLC	19–100–NG
BORDER ENERGY MANAGEMENT LLC	19–102–NG
MINNESOTA ENERGY RESOURCES CORPORATION)	19–106–NG
PACIFIC GAS AND ELECTRIC COMPANY	19–103–NG
ALTAGAS LTD	19–83–NG
PIONEER LNG, LLC	19–87–NG
UNITED ENERGY TRADING CANADA, ULC	19–108–NG
WISCONSIN GAS LLC	19–111–NG
WISCONSIN ELECTRIC POWER COMPANY	19–110–NG
TENASKA MARKETING VENTURES	19–109–NG
CITY OF PORTAL, INCORPORATED	19–101–NG
DTE ENERGY TRADING, INC	19–107–NG
SOCIETE GENERALE ENERGY LLC	19–22–NG

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 September 2019, it issued orders granting authority to import and export natural gas, to import and export liquefied natural gas (LNG), to import and export compressed natural gas (CNG), and vacating authorization. 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-2019.*

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.

Signed in Washington, DC, on October 18, 2019.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Oil and Natural Gas.

Appendix

DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS

4423	09/03/19	19–93–LNG	Gabza International Gas Inc	Order 4423 granting blanket authority to export LNG to Mexico by truck.
4426	09/03/19	19–88–NG	Tidal Energy Marketing (U.S.) L.L.C	Order 4426 granting blanket authority to import/export natural gas from/to Canada.
4427	09/03/19	19–82–NG	TransAlta Energy Marketing (U.S.) Inc	Order 4427 granting blanket authority to import/export natural gas from/to Canada.
4428	09/03/19	19–97–CNG	Pentagon Energy, LLC	Order 4428 granting blanket authority to export CNG to Mexico by vessel/truck.
4429	09/03/19	19–94–NG	Cenovus Energy Marketing Limited	Order 4429 granting blanket authority to import natural gas from Canada.
4430	09/03/19	19–98–NG	San Diego Gas & Electric Company	Order 4430 granting blanket authority to import/export natural gas from/to Mexico.
4431	09/03/19	19–96–NG	Just Energy New York Corp	Order 4431 granting blanket authority to import/export natural gas from/to Canada.
4432	09/03/19	19–70–NG	Valence Natural Gas Solutions LLC	Order 4432 granting blanket authority to import/export CNG from/to Canada, and vacating prior authorization, Order 4196.
4433	09/03/19	19–100–NG	EDF Trading North America, LLC	Order 4433 granting blanket authority to import/export natural gas from/to Canada/Mexico, to import/export LNG from/to Canada/Mexico by truck, to export LNG to Canada/Mexico by vessel, and to import LNG from various international sources by vessel.
4434	09/03/19	19–102–NG	Border Energy Management LLC	Order 4434 granting blanket authority to export natural gas to Mexico.
4435	09/06/19	19–106–NG	Minnesota Energy Resources Corporation.	Order 4435 granting blanket authority to import/export natural gas from/to Canada.
4436	09/09/19	19–103–NG	Pacific Gas and Electric Company	Order 4436 granting blanket authority to import natural gas from Canada.
4437	09/09/19	19–83–NG	AltaGas Ltd.	Order 4437 granting authority to import/export natural gas from/to Canada.
4438	09/10/19	19–87–NG	Pioneer LNG, LLC	Order 4438 granting blanket authority to import/export natural gas from/to Canada/Mexico.
4439	09/30/19	19–108–NG	United Energy Trading Canada, ULC	Order 4439 granting blanket authority to import/export natural gas from/to Canada.
4440	09/30/19	19–111–NG	Wisconsin Gas LLC	Order 4440 granting blanket authority to import/export natural gas from/to Canada.
4441	09/30/19	19–110–NG	Wisconsin Electric Power Company	Order 4441 granting blanket authority to import/export natural gas from/to Canada.
4442	09/30/19	19–109–NG	Tenaska Marketing Ventures	Order 4442 granting blanket authority to import/export natural gas from/to Canada/Mexico.
4443	09/30/19	19–101–NG	City of Portal, Incorporated	Order 4443 granting blanket authority to import natural gas from Canada.
4444	09/30/19	19–107–NG	DTE Energy Trading, Inc.	Order 4444 granting blanket authority to import/export natural gas from/to Canada.
4350–A	09/30/19	19–22–NG	Societe Generale Energy LLC	Order 4350–A vacating blanket authority to import/export natural gas from/to Canada/Mexico.

[FR Doc. 2019–23326 Filed 10–24–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 5069–012]

Kingdom Energy Products; Hillside Clean Energy LLC; Notice of Transfer of Exemption

1. On July 3, 2019, Kingdom Energy Products, exemptee for the Sygitowicz Creek Power Project No. 5069, filed a letter notifying the Commission that the project was transferred from Kingdom Energy Products to Hillside Clean Energy LLC. The exemption from licensing was originally issued on July 14, 1982.[1] The project is located on the Sygitowicz Creek, Whatcom County, Washington. The transfer of an exemption does not require Commission approval.

2. Hillside Clean Energy LLC is now the exemptee of the Sygitowicz Creek Hydro Project No. 5069. All correspondence must be forwarded to: Mr. Steven TeVelde, P.O. Box 895, Lynden, WA 98264, Phone: 360–305–2628, Email: *stevetevelde@gmail.com.*

Dated: October 21, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–23324 Filed 10–24–19; 8:45 am]

BILLING CODE 6717–01–P

[1] *Douglas S. Marr,* 20 FERC ¶ 62,051 (1982). Kingdom Energy Products acquired the rights to construct the project in 1984.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2413–126]

Georgia Power Company; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection:

a. *Type of Application:* Non-Project Use of Project lands and Waters—Sand Mine.

b. *Project No.:* 2413–126.

c. *Date Filed:* August 30, 2019.

d. *Applicant:* Georgia Power Company (licensee).

e. *Name of Project:* Wallace Pumped Storage Hydroelectric Project.

f. *Location:* The proposed non-project sand mine is located in the northern

part of Lake Oconee, the project reservoir, in Greene County, Georgia.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Herbie Johnston, Hydro General Manager, 600 North 18th Street, Bin 16N–8180, Birmingham, AL 35203.

i. *FERC Contact:* Michael Calloway at (202) 502–8041 or *michael.calloway@ferc.gov*.

j. Deadline for filing comments, motions to intervene, and protests is 30 days from the issuance of this notice by the Commission. The Commission strongly encourages electronic filing. Please file motions to intervene, protests, and comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–2413–126.

k. *Description of Request:* The license filed a request to permit a non-project use of project lands and waters to allow River Sand Incorporated to dredge throughout an approximately 2-mile stretch of the upper project reservoir in Greene County, Georgia for the purposes of commercial sand mining. The sorting area will be located on 6 acres of privately-owned land within the project boundary that the licensee has flowage rights over. The mine operator expects the year round operation of the sand mine will extract 5,000 to 25,000 tons of sediment per year. The operation will not be conducted on U.S. Forest Service Land.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE, Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's website at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call (866) 208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title COMMENTS; PROTEST, or MOTION TO INTERVENE as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to the non-project use application. Agencies may obtain copies of plans directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: October 21, 2019.

Kimberly D. Bose,

Secretary.

[FR Doc. 2019–23325 Filed 10–24–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Southwestern Power Administration

Continuation of Temporary Power Sales Program

AGENCY: Southwestern Power Administration, DOE.

ACTION: Notice of acceptance of new applications under Southwestern Power Administration's Temporary Power Sales Program.

SUMMARY: Southwestern Power Administration (Southwestern) is accepting new applications under its Temporary Power Sales Program. Electric utility organizations interested in participating in the Temporary Power Sales Program should notify Southwestern of their interest by providing the information requested in the enclosed Resource Data Form B–2 and/or Resource Data Form L–2 to Southwestern.

DATES: Completed forms (Resource Data Form B–2 and/or Resource Data Form L–2) will be accepted beginning on October 25, 2019 and ending on December 9, 2019.

ADDRESSES: Completed forms and any questions or comments should be submitted to Ms. Fritha Ohlson, Senior Vice President/COO, Southwestern Power Administration, U.S. Department of Energy, 1 W 3rd St., Suite 1600, Tulsa, Oklahoma 74103.

FOR FURTHER INFORMATION CONTACT: Ms. Fritha Ohlson, Senior Vice President/COO, 918–595–6684, *fritha.ohlson@swpa.gov,* facsimile transmission 918–595–6656.

SUPPLEMENTARY INFORMATION: Southwestern markets Federal hydroelectric power and energy from projects constructed and operated by the U.S. Army Corps of Engineers located in the states of Arkansas, Missouri, Oklahoma, and Texas, under the provisions of Section 5 of the Flood Control Act of 1944 (16 U.S.C. 825s), as amended, in an area which includes the previously-mentioned states plus Kansas and Louisiana.

By **Federal Register** notice dated June 18, 1987 (52 FR 23206) (1987 FRN), Southwestern implemented the Temporary Power Sales Program, wherein an existing Southwestern customer can make all or a portion of its

allocated Federal hydroelectric power and energy from Southwestern (allocation) available to Southwestern for temporary sale to others in the following priority: (1) Public body and cooperative electric utility systems that are present or potential customers (including joint action agencies and any other public body and/or cooperative electric utility organizations that may be able to distribute the benefits of Federal hydroelectric power and energy to said public body and cooperative electric utility systems), and (2) electric utilities other than public body and/or cooperative electric utility systems to be selected if no public body and cooperative electric utility systems are available to purchase such Federal hydroelectric power and energy. Entities participating in the program are referred to as ''loaners'' and ''borrowers.''

Southwestern followed up on the Temporary Power Sales Program with a letter sent to its customers October 14, 1988 (October 1988 letter). The October 1988 letter solicited additional interest in the Temporary Power Sales Program and stated Southwestern's intention of maintaining electric utility data on a biennial basis, with the lists of loaners and borrowers to be renewed every two years. To date, Southwestern has reviewed the program three times: In 1989, in 1992, and in 2019.

The first two reviews of the program yielded no change to the lists of loaners and borrowers. The latest review in 2019 resulted in the deletion of participants whose applications had expired based on the ''Stop Borrowing'' date in the Resource Data Form, leaving six participants still active in the program.

The 2019 review was initiated after Southwestern received an offer of a loan under the Temporary Power Sales Program from Southwestern's customers which receive the output of the Robert D. Willis Hydropower Project (Willis), located in southeast Texas. These customers offered all capacity and energy from Willis for loan to others for a duration to be determined. Operating characteristics of Willis are enclosed for reference.

In response to the loan offer, Southwestern notified the six remaining participants in the program and solicited their interest in the output of Willis. All six participants expressed their interest in staying in the program, but none were interested in the output of Willis.

Southwestern has been notified recently that two other customers are interested in making all or a portion of their respective allocations available to Southwestern for sale under the Temporary Power Sales Program.

Based on the potential Willis loan and the potential loan from these two other customers, Southwestern estimates that there may be up to 10 megawatts (MW) of Federal hydroelectric power and associated energy available for sale under one or more of Southwestern's rate schedules governing the sale and purchase of Federal hydroelectric power and energy. After the close of this request for applications to the Temporary Power Sales Program, Southwestern will have more certain information on the allocations available for sale under the Temporary Power Sales Program.

Southwestern intends to use the procedure described in the 1987 FRN to implement the acceptance of new applications under the Temporary Power Sales Program, wherein the selection of loaners and borrowers is based on data provided by the participants. The selection process may generate a new list of applicants under the program. The six entities currently considered to be active in the program will be allowed to remain in the program with their original chronological receipt dates until the earlier of (1) the date an entity submits a new application; or (2) the date of the next biennial review.

Interested parties are requested to complete Resource Data Forms containing information pertinent to the Temporary Power Sales Program. The Resource Data Forms will be accepted during the period specified in this **Federal Register** Notice (see **DATES**). Resource Data Forms received after that period will be accepted for chronological receipt date purposes but may not be considered for participation in the program until such time as Southwestern conducts another review of the Temporary Power Sales Program, tentatively scheduled for 2021.

Submission of Resource Data Forms in no way obligates an applicant to loan or borrow under the Temporary Power Sales Program. If a match is identified, Southwestern will work with the loaner and borrower to document the sale. Conversely, submission of Resource Data Forms in no way obligates Southwestern to make any sales under the Temporary Power Sales Program. Such sales will be made at the sole discretion of Southwestern.

Southwestern will analyze the information provided and, at its discretion, will match loaners and borrowers per the criteria identified herein. Only in the event that more than one loaner or borrower is available for the same temporary sale will a decision be made based on the chronological receipt of Resource Data Forms, including those still active under the original 1987 FRN or the October 1988 letter.

Allocations made available to Southwestern under the Temporary Power Sales Program will be sold on a temporary basis, and for an initial period of not less than one (1) year, provided the selected borrower or borrowers have, or must be able to arrange, the transmission rights to receive such Federal hydroelectric power and energy.

Therefore, in accordance with the priority expressed herein, Southwestern is hereby issuing this ''Notice of Acceptance of New Applications Under Southwestern Power Administration's Temporary Power Sales Program.''

Electric utility organizations interested in participating in the Temporary Power Sales Program should notify Southwestern of their interest by providing the information requested in the enclosed Resource Data Form B–2 and/or Resource Data Form L–2 to Southwestern (see **DATES**). To assist Southwestern in best matching loaners and borrowers, applicants are encouraged to use the ''Additional information'' section at the bottom of the forms to describe specific resources they want to borrow or loan. Fillable versions of these forms will also be made available on Southwestern's internet site at *https://www.swpa.gov.*

Based on the responses received, Southwestern, at its sole discretion, may elect to hold one or more public meetings to afford all responders equal opportunity to have their responses addressed.

Dated: October 10, 2019.

Mike Wech,

Administrator.

Southwestern Power Administration (SWPA)

Hydroelectric Power Borrowing Program

Resource Data Form B-2

Name of Utility System _____

Address _____

Utility Manager _____

Telephone Number _____

1. Is your utility interested now, or in the near future, in borrowing Federal hydroelectric power that is available for loan on a temporary basis for distribution by SWPA?

Federal Capacity Only	Federal Energy Only	Both Federal Capacity and Federal Energy
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No

2. If yes, please indicate the quantities and types of Federal hydroelectric power your utility would be interested in borrowing and the desired time frames.

	Federal Capacity Only	Federal Energy Only	Both Federal Capacity and Energy	
	kW	kWh	kW	kWh
Quantity	_____	_____	_____	_____

Start Borrowing (Day, Month, Year) _____

Stop Borrowing (Day, Month, Year) _____

Additional information (optional): _____

_____

_____

_____

3. Does your utility have the transmission rights or is your utility able to arrange the transmission rights to receive Federal hydroelectric power from SWPA?

[ ] Yes [ ] No

If yes, describe the transmission rights in detail. _____

_____

_____

_____

_____

_____

Southwestern Power Administration (SWPA)

Hydroelectric Power Loaning Program

Resource Data Form L-2

Name of Utility System _____

Address _____

Utility Manager _____

Telephone Number _____

1. Does your utility presently have, or expect to have in the near future, Federal hydroelectric power that is available for loan on a temporary basis for distribution by SWPA?

Federal Capacity Only	Federal Energy Only	Both Federal Capacity and Federal Energy
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No

2. If yes, please indicate the quantities and types of Federal hydroelectric power your utility is willing to loan and the time frames available.

	Federal Capacity Only kW	Federal Energy Only kWh	Both Federal Capacity and Energy kW	kWh
Quantity	_____	_____	_____	_____

Begin Loan (Day, Month, Year) _____

End Loan (Day, Month, Year) _____

Additional information (optional): _____

_____

_____

_____

_____

_____

_____

_____

Robert D. Willis Hydropower Project Characteristics

Capacity and Sales Information

Capacity: 7.4 Megawatts (MW).

Annual Power Sales Rate (includes capacity and energy costs): $1,282,836/year.[1]

Monthly Power Sales Rate (includes capacity and energy costs): $106,903/month.[1]

Energy Information

Based on the historical[2] actual average annual energy of 25,278 Megawatt-hours (MWh) (3,349 hours), the composite cost is $50.75/MWh.

Based on the historical[2] actual maximum annual energy of 40,097 MWh (5,455 hours), the composite cost is $31.99/MWh.

Based on the historical[2] actual minimum annual energy of 0 MWh (0 hours), the composite cost is $1,282,839 for no MWh.

Based on the estimated[3] annual energy of 37,260 MWh (5,069 hours), the composite cost is $34.43/MWh.

Other Information

The Robert D. Willis Hydropower Project has had operational challenges for the past 10 years. Approximately $7,090,000 of capital equipment repair

[1] Under rate schedule RDW–15, currently in-effect through September 30, 2021.

[2] Historical period is calendar years 1990–2018.

[3] Estimated annual energy is from a USACE planning study prior to project construction.

and replacement, already included in the power sales rate listed above, needs to be undertaken to correct many of the challenges experienced at the project. It is estimated that this work will take a minimum of three years to complete.

The point of delivery for the Robert D. Willis Hydropower Project is at the Robert D. Willis Hydropower Project switchyard, which is interconnected to the electric grid by a distribution system owned by Jasper-Newton Electric Cooperative. A separate agreement with Jasper-Newton Electric Cooperative may be required to transmit the power and associated energy from the Robert D. Willis Hydropower Project to the Mid-Continent Independent System Operator (MISO).

[FR Doc. 2019–23373 Filed 10–24–19; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2019–0271; FRL–9999–46]

Certain New Chemicals or Significant New Uses; Statements of Findings for July 2019

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(g) of the Toxic Substances Control Act (TSCA) requires EPA to publish in the **Federal Register** a statement of its findings after its review of TSCA section 5(a) notices when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to premanufacture notices (PMNs), microbial commercial activity notices (MCANs), and significant new use notices (SNUNs) submitted to EPA under TSCA section 5. This document presents statements of findings made by EPA on TSCA section 5(a) notices during the period from July 1, 2019 to July 31, 2019.

FOR FURTHER INFORMATION CONTACT:

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

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitters of the PMNs addressed in this action.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2019–0271, 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.*

II. What action is the Agency taking?

This document lists the statements of findings made by EPA after review of notices submitted under TSCA section 5(a) that certain new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment. This document presents statements of findings made by EPA during the period from July 1, 2019 to July 31, 2019.

III. What is the Agency's authority for taking this action?

TSCA section 5(a)(3) requires EPA to review a TSCA section 5(a) notice and make one of the following specific findings:

- The chemical substance or significant new use presents an unreasonable risk of injury to health or the environment;
- The information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance or significant new use;
- The information available to EPA is insufficient to permit a reasoned evaluation of the health and environmental effects and the chemical substance or significant new use may present an unreasonable risk of injury to health or the environment;
- The chemical substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance; or
- The chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment.

Unreasonable risk findings must be made without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant under the conditions of use. The term ''conditions of use'' is defined in TSCA section 3 to mean ''the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.''

EPA is required under TSCA section 5(g) to publish in the **Federal Register** a statement of its findings after its review of a TSCA section 5(a) notice when EPA makes a finding that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment. Such statements apply to PMNs, MCANs, and SNUNs submitted to EPA under TSCA section 5.

Anyone who plans to manufacture (which includes import) a new chemical substance for a non-exempt commercial purpose and any manufacturer or processor wishing to engage in a use of a chemical substance designated by EPA as a significant new use must submit a notice to EPA at least 90 days before commencing manufacture of the new chemical substance or before engaging in the significant new use.

The submitter of a notice to EPA for which EPA has made a finding of ''not likely to present an unreasonable risk of injury to health or the environment'' may commence manufacture of the chemical substance or manufacture or processing for the significant new use notwithstanding any remaining portion of the applicable review period.

IV. Statements of Administrator Findings Under TSCA Section 5(a)(3)(C)

In this unit, EPA provides the following information (to the extent that such information is not claimed as Confidential Business Information

(CBI)) on the PMNs, MCANs and SNUNs for which, during this period, EPA has made findings under TSCA section 5(a)(3)(C) that the new chemical substances or significant new uses are not likely to present an unreasonable risk of injury to health or the environment:

• EPA case number assigned to the TSCA section 5(a) notice.

• Chemical identity (generic name, if the specific name is claimed as CBI).

• Website link to EPA's decision document describing the basis of the ''not likely to present an unreasonable risk'' finding made by EPA under TSCA section 5(a)(3)(C).

EPA case No.	Chemical identity	Website link
P–18–0035	Methacrylic acid heterocyclic alkyl ester (generic name)	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-275.*
P–18–0009	Phosphonic acid, dimethyl ester, polymer with alkyl diols (generic name).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-274.*
P–17–0395	Alkyl tri dithiocarbmate tri salt (generic name)	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-273.*
P–17–0346	Phosphonium, triphenylpropyl-, bromide (CASRN: 6228–47–3)	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-272.*
P–17–0312, P–17–0313, P–17–0314, P–17–0315, P–17–0316, P–17–0317.	(P–17–0312) Organic acid, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted amine-disubstituted polypropylene glycol reaction products; (P–17–0313) Phenol, 4,4′-(1-methylethylidene) bis-, polymer with 2-(chloromethyl)oxirane and alpha-(2-oxiranylmethyl)-omega-(2-oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], reaction products with disubstituted amine and disubstituted polypropylene glycol, organic acid salts; (P–17–0314) Organic acid, 2-substituted-, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted aminedisubstituted polypropylene glycol reaction products; (P–17–0315) Phenol, 4,4′-(1-methylethylidene)bis-, polymer with alpha-(2-substituted-methylethyl)-omega-(2-substituted-methylethoxy)poly[oxy (methyl-1,2-ethanediyl)], 2-(chloromethyl)oxirane and alpha-(2-oxiranylmethyl)-omega-(2-oxiranylmethoxy)poly[oxy(methyl-1,2-ethanediyl)], alkylphenyl ethers, reaction products with disubstituted amine, organic acid salts; (P–17–0316) Organic acid, compds. with bisphenol A-epichlorohydrin-disubstituted polypropylene glycol-polypropylene glycol diglycidyl ether polymer alkylphenyl ethers-disubstituted amine reaction products; (P–17–0317) Organic acid, compds. with bisphenol A-epichlorohydrin-polypropylene glycol diglycidyl ether polymer-disubstituted polypropylene glycol reaction products (generic names).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-271.*
P–19–0096	Benzofuranone, bis(branched alkyl)-[dialkyl[tetrakis(branched alkyl)-alkyl-dibenzo-substitutedphosphite-yl] phenyl]- (generic name).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-270.*
P–19–0062	Hydrochlorofluoroolefin (generic name)	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-269.*
P–19–0029	Phosphonium, tributylethyl-, diethyl phosphate (1:1) (CASRN: 20445–94–7).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-268.*
P–18–0394	Substituted benzylic ether polyethylene glycol alkyl ether derivative (generic name).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-267.*
P–18–0300	Heteromonocycle, alkenoic 1:1 salt, polymer with alpha-(2-methyl-1-oxo-2-propen-1-y)l-omegamethoxypoly(oxy-1,2-ethanediyl) and methylalkenoic acid (generic name).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-266.*
P–18–0286	Propane, 1,1,1,3,3,3-hexafluoro-2-methoxy- (CASRN: 13171–18–1).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-265.*
P–18–0257	Phosphoric acid, potassium salt (2:3) (CASRN: 66923–00–0)	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-264.*
P–18–0103	Alkylnitrile imidazole (generic name)	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-263.*
P–16–0442, P–16–0443, P–16–0444, P–16–0445.	(P–16–0442) Carboxylic acids, unsaturated, polymers with disubstituted amine, alkanediol, substituted alkylpropanoic acid, alkanedioic acid and substituted isocyanatocycloalkane, compds with alkylamine; (P–16–0443) Carboxylic acids, unsaturated, hydrogenated polymers with disubstituted amine, alkanediol, substituted alkylpropanoic acid, alkanedioic acid and substituted isocyanatocycloalkane, compds with alkylamine; (P–16–0444) Carboxylic acids, unsaturated, polymers with substituted alkanediamine, alkanediol, substituted alkylpropanoic acid, alkanedioic acid and substituted isocyanatocycloalkane, compds with alkylamineAmine salted polyurethane; (P–16–0445) Carboxylic acids, unsaturated, hydrogenated polymers with substituted alkanediamine, alkanediol, substituted alkylpropanoic acid, alkanedioic acid and substituted isocyanatocycloalkane, compds with alkylamine (generic names).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-262.*
P–16–0092	Polymeric polyamine (generic name)	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-261.*
P–18–0401	Glycerides, C16-18 and CI8-unsatd. mono- and di-, citrates (CASRN: 91052–16–3).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-260.*
P–18–0177	Waxes and Waxy substances, rice bran, oxidized (CASRN: 1883583–80–9).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-259.*
P–17–0362	Aliphatic phosphoric amide ester (generic name)	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-258.*

EPA case No.	Chemical identity	Website link
P–19–0081	2-Propenoic acid, alkyl ester, reaction products with mixed substituted alkyl esters of phosphorodithioic acid and propylene oxide (generic name).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-257.*
P–18–0185	Fatty acid, polymer with alkanedioic acid dialkyl ester, hydroxyl alkyl substituted alkanediol, substituted carbomonocycle and alkylol substituted alkane (generic name); polymer exemption flag.	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-256.*
P–18–0285	Specific: Butanedioic acid, 2-methylene-, polymer with 2-methyl-2-[(1-oxo-2-propen-1-yl)amino]-1-propanesulfonic acid, sodium zinc salt (CASRN: 2220235–78–7).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-255.*
P–18–0223	Alkane, bis(alkoxymethyl)-dimethyl- (generic name)	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-254.*
P–19–0068	1,4-benzenedicarboxylic acid, polymer with diol, 5-amino-1,3,3-trimethylcyclohexanemethanamine, 1,2-ethanediol and urea (generic name).	*https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-253.*

Authority: 15 U.S.C. 2601 *et seq.*

Dated: October 3, 2019.

Leo Schweer,

Chief, New Chemicals Management Branch, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 2019–23370 Filed 10–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2019–0039; FRL–10001–13]

Pesticide Product Registration; Receipt of Applications for New Active Ingredients (September 2019)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before November 25, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the File Symbol of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

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

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

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

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

New Active Ingredients

1. *File Symbol:* 91213–G. *Docket ID number:* EPA–HQ–OPP–2017–0336. *Applicant:* United States Department of Agriculture-Agricultural Research Service, 920 Valley Road, Reno NV 89512. *Product name:* Battalion Pro. *Active ingredient:* Herbicide—*Pseudomonas fluorescens* strain ACK55 at 100%. *Proposed use:* End use product. For suppression of cheat grass/downy brome, medusahead, and jointed goat grass through use as a seed treatment or a spray in the following areas: Crops (*i.e.,* cereal grains and forage, fodder, and straw of cereal grains; grass forage, fodder, and hay; non-grass animal feeds; oilseeds; legumes; tree nuts; and berries and small fruit), rangeland, forest, pasture, turf, conservation reserve program lands, sod production, golf courses,

recreational areas, road sides, road cuts, construction sites, and rights-of-way. *Contact:* BPPD.

2. *File Symbol:* 91213–U. *Docket ID number:* EPA–HQ–OPP–2017–0336. *Applicant:* United States Department of Agriculture-Agricultural Research Service, 920 Valley Road, Reno NV 89512. *Product name: Pseudomonas fluorescens* strain ACK55 Technical. *Active ingredient:* Herbicide—*Pseudomonas fluorescens* strain ACK55 at 100%. *Proposed use:* Manufacturing use product. *Contact:* BPPD.

3. *File Symbol:* 93566–R. *Docket ID number:* EPA–HQ–OPP–2019–0550. *Applicant:* G.D.G Environment, 430 Rue Saint-Laurent, Trois-Rivieres (Quebec) G8T 6H3 Canada c/o Technology Sciences Group, USA, 1150 18th Street NW, Washington, DC 20036. *Product name:* Fraxiprotec. *Active ingredient:* Insecticide—*Beauveria bassiana* strain CFL-A at 12%. *Proposed use:* End use product/Control Emerald Ash Borer Beetle. *Contact:* BPPD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 10, 2019.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2019–23361 Filed 10–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9047–6]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa/.*

Weekly receipt of Environmental Impact Statements

Filed 10/14/2019 10 a.m. ET Through 10/21/2019 10 a.m. ET

Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20190255, Draft Supplement, NRC, VA, Generic Environmental Impact Statement for License Renewal of Nuclear Plants—Supplement 6, Second Renewal Regarding Subsequent License Renewal for Surry Power Station Units 1 and 2, Comment Period Ends: 12/10/2019, Contact: Tam Tran 301–415–3617

EIS No. 20190256, Draft Supplement, NASA, CA, Draft Supplemental Environmental Impact Statement for Soil Cleanup Activities at Santa Susana Field Laboratory, Comment Period Ends: 12/09/2019, Contact: Peter Zorba *msfc-ssfl-information@mail.nasa.gov*

EIS No. 20190257, Final, RUS, WI, Cardinal-Hickory Creek 345-kV Transmission Line Project, Review Period Ends: 11/25/2019, Contact: Dennis Rankin 202–720–1953

EIS No. 20190258, Draft Supplement, NASA, FL, Supplemental Environmental Impact Statement for the Mars 2020 Mission, Comment Period Ends: 12/10/2019, Contact: George Tahu 202–358–0016

EIS No. 20190259, Final, BR, CA, Mendota Pool Group 20-Year Exchange Program, Review Period Ends: 11/25/2019, Contact: Rain Emerson 559–262–0335

EIS No. 20190260, Draft, BR, USACE, CA, Port of Long Beach Deep Draft Navigation Feasibility Study, Comment Period Ends: 12/09/2019, Contact: Larry Smith 213–452–3846

Amended Notice

EIS No. 20190254, Draft, USFS, AK, Rulemaking for Alaska Roadless Areas, Comment Period Ends:12/17/2019, Contact: Ken Tu 202–403–8991

Revision to FR Notice Published 10/18/2019; Correction to Comment Period Due Date from December 18, 2019 to December 17, 2019.

Dated: October 21, 2019.

Robert Tomiak,

Director, Office of Federal Activities.

[FR Doc. 2019–23313 Filed 10–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2019–0045; FRL–10001–12]

Pesticide Product Registration; Receipt of Applications for New Uses (September 2019)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before November 25, 2019.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number and the File Symbol of the EPA registration number of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

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

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), main telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov.* Anita Pease, Antimicrobials Division (AD) (7510P), main telephone number: (703) 305–7090; email address: *ADFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

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).

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

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

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

New Uses

1. *EPA Registration Numbers:* 264–1143, 264–1141, 264–1142. *Docket ID Number:* EPA–HQ–OPP–2019–0460. *Applicant:* Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. *Active ingredient:* Flupyradifurone. *Product type:* Insecticide. *Proposed use:* Foliar use for rapeseed sub crop group 20A, canola seed treatment. *Contact:* RD.

2. *File Symbol:* 538–GGI. *Docket ID number:* EPA–HQ–OPP–2019–0559. *Applicant:* The Scotts Company LLC, 14111 Scottslawn Rd., Marysville, OH 43041. *Product name:* Scotts ZeroScrub Cleaner Conc/RTS. *Active ingredient:* Nonanoic acid at 2.0%. *Product type:* Antimicrobial. *Proposed uses:* End-use product as a one-step liquid cleaner, for outdoor residential use for moss, mold, mildew, and algae removal, control, and stain removal. *Contact:* AD.

3. *File Symbol:* 538–GGO. *Docket ID number:* EPA–HQ–OPP–2019–0559. *Applicant:* The Scotts Company LLC, 14111 Scottslawn Rd., Marysville, OH 43041. *Product name:* Scotts ZeroScrub Cleaner RTU. *Active ingredient:* Nonanoic acid at 0.1%. *Product type:* Antimicrobial. *Proposed uses:* End-use product as a one-step liquid cleaner, for outdoor residential use for moss, mold, mildew, and algae removal, control, and stain removal. *Contact:* AD.

4. *EPA Registration Numbers:* 59639–107, 59639–202. *Docket ID number:* EPA–HQ–OPP–2018–0644. *Applicant:* Interregional Research Project Number 4 (IR–4), IR–4 project Headquarters, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08450. *Active ingredient:* Etoxazole. *Product type:* Insecticide. *Proposed use:* Beet, sugar, roots; beet, sugar, leaves. *Contact:* RD.

5. *EPA Registration Numbers:* 66330–403, 66330–404. *Docket ID number:* EPA–HQ–OPP–2019–0389. *Applicant:* Arysta LifeScience North America LLC, 15401 Weston Parkway, Suite 150, Cary, NC 27513. *Active ingredient:* Kasugamycin. *Product type:* Fungicide/Bactericide. *Proposed use:* Peach subgroup 12–12B, apricot and almond. *Contact:* RD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: October 10, 2019.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2019–23353 Filed 10–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2019–0058; FRL–10000–93]

Pesticide Program Dialogue Committee (PPDC); Notice of Charter Renewal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given that the Environmental Protection Agency has determined that, in accordance with the provisions of the Federal Advisory Committee Act (FACA), the Pesticide Program Dialogue Committee (PPDC) is in the public interest and is necessary in connection with the performance of EPA's duties. Accordingly, PPDC will be renewed for an additional two-year period. The purpose of PPDC is to provide advice and recommendations to the EPA Administrator on issues associated with regulatory development and reform initiatives, evolving public policy and program implementation issues, and science issues associated with evaluating and reducing risks from use of pesticides.

FOR FURTHER INFORMATION CONTACT: Shannon Jewell, Designated Federal Officer, Pesticide Program Dialogue Committee (PPDC), U.S. EPA, 1200 Pennsylvania Ave. NW (mail code 7501P), Washington, DC 20460, Telephone: 703–347–0109, Email: *jewell.shannon@epa.gov.*

Authority: 5 U.S.C. App.2.

Dated: October 10, 2019.

Richard Keigwin,

Director, Office of Pesticide Programs.

[FR Doc. 2019–23390 Filed 10–24–19; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2018–0014; FRL–10000–07]

Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations and Amend Registrations To Terminate Certain Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by the registrants to voluntarily cancel certain pesticide product registrations and to amend certain product registrations to terminate uses. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw their requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registrations have been cancelled and uses terminated only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before November 25, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2018–0014, by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be

Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

Submit written withdrawal request by mail to: Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. ATTN: Christopher Green.

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

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

FOR FURTHER INFORMATION CONTACT:

Christopher Green, Information Technology and Resources Management Division (7502P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 347–0367; email address: *green.christopher@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

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

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

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

II. What action is the Agency taking?

This notice announces receipt by EPA of requests from registrants to cancel certain pesticide products and amend product registrations to terminate certain uses registered under FIFRA section 3 (7 U.S.C. 136a) or 24(c) (7 U.S.C. 136v(c)). The affected products and the registrants making the requests are identified in Tables 1–3 of this unit.

Unless a request is withdrawn by the registrant or if the Agency determines that there are substantive comments that warrant further review of this request, EPA intends to issue an order in the **Federal Register** canceling and amending the affected registrations.

TABLE 1—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Company No.	Product name	Active ingredients
228–709	228	Super Boll	Ethephon.
464–782	464	Aqucar PS 20 Water Treatment Microbiocide	Tetrakis(hydroxymethyl)phosphonium sulphate (THPS).
464–8126	464	Aqucar PS 75 Water Treatment Microbiocide	Tetrakis(hydroxymethyl)phosphonium sulphate (THPS).
464–8127	464	Aqucar THPS 75MFG Water Treatment Microbiocide	Tetrakis(hydroxymethyl)phosphonium sulphate (THPS).
464–8129	464	Aqucar PS 75C MUP Water Treatment Microbiocide	Tetrakis(hydroxymethyl)phosphonium sulphate (THPS).
1258–1279	1258	Pool Breeze Pool Care System Shock 35	Lithium hypochlorite.
1381–227	1381	Imidacloprid 75% WSP Turf, Insecticide	Imidacloprid.
2792–28	2792	Deccosol 122 Concentrate	o-Phenylphenol, sodium salt.
2792–54	2792	Deccosan 315	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12 & Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14).
7313–25	7313	Clear Wood Preservative	Folpet & Carbamic acid, butyl-, 3-iodo-2-propynyl ester.
7364–94	7364	Poolcare Lithium	Lithium hypochlorite.
8660–150	8660	Vertagreen Fertilizer With 1% Surflan	Oryzalin.
34688–80	34688	Aquatreat DNM–9	Nabam & Sodium dimethyldithiocarbamate.
34688–81	34688	Aquatreat DNM–360	Nabam & Sodium dimethyldithiocarbamate.
45728–29	45728	SDDC	Sodium dimethyldithiocarbamate.
57787–14	57787	Crystal Shock	Lithium hypochlorite.
62719–605	62719	Clincher EZ	Cyhalofop-butyl.
62719–613	62719	Clincher GR	Cyhalofop-butyl.
62719–647	62719	Clincher Granule	Cyhalofop-butyl.
62719–651	62719	Clincher 5G	Cyhalofop-butyl.
69681–7	69681	Clor Mor Lithium Shock	Lithium hypochlorite.
69681–35	69681	Clor Mor Silver Algaecide	Nanosilver 002.
70127–2	70127	Novozymes Biofungicide Green Releaf 710–140	Bacillus licheniformis strain SB3086 & Indole-3-butyric acid.
70127–3	70127	Novozymes Biofungicide 145F	Indole-3-butyric acid & Bacillus licheniformis strain SB3086.
85678–54	85678	Flucarbazone Technical	Flucarbazone-sodium.

TABLE 1—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration No.	Company No.	Product name	Active ingredients
87663–2	87663	Emery Agro 7010 Ready-To-Use (RTU)	Pelargonic acid, ammonium salt.
87663–4	87663	Emery Agro 7030 Concentrate	Pelargonic acid, ammonium salt.
87663–5	87663	Emery Agro 7040 Ready-To-Use (RTU)	Pelargonic acid, ammonium salt.
87663–6	87663	Emerion 7001 Concentrate	Pelargonic acid, ammonium salt.
87663–7	87663	Emerion 7031 Concentrate	Pelargonic acid, ammonium salt.
87703–1	87703	8 in 1 Bird Protector	Paradichlorobenzene.
88356–1	88356	Niccanon ZP–700	Zinc pyrithione.
CA–070010	71711	Talus 40 SC Insect Growth Regulator	Buprofezin.
CA–080013	62719	Lorsban Advanced	Chlorpyrifos.
CA–140001	70506	Manzate Pro-Stick Fungicide	Mancozeb.
CO–030009	400	Terrazole 4EC	Etridiazole.
CO–070004	66222	Rimon 0.83 EC	Novaluron.
KS–170003	10163	Treflan TR–10	Trifluralin.
OR–060021	66222	Rimon 0.83 EC	Novaluron.
OR–080024	279	Fyfanon ULV AG	Malathion (NO INERT USE).
OR–160011	279	Exirel Insect Control	Cyantraniliprole.
SD–150001	62719	Enlist Duo	2,4-D, Choline salt & Glycine, N-(phosphonomethyl)-, compd. with N-methylmethanamine (1:1).
TX–060016	56228	Compound DRC–1339 Concentrate—Livestock, Nest & Fodder Depredations.	Starlicide.
UT–170006	10163	Treflan TR–10	Trifluralin.
WA–020030	264	Aliette WDG Fungicide	Fosetyl-Al.

TABLE 2—PRODUCT REGISTRATIONS WITH PENDING REQUESTS FOR AMENDMENT

Registration No.	Company No.	Product name	Active ingredient	Uses to be terminated
1475–21	1475	Paradichlorobenzene	Paradichlorobenzene	Bird cage use.
42750–148	42750	Propazine 4L	Propazine	Greenhouse use.
42750–149	42750	Propazine Technical	Propazine	Greenhouse use.
46923–11	46923	Copper Sulfate Pentahydrate Technical.	Copper sulfate pentahydrate	Wood preservative use.
80990–3	80990	Agri-Seed 50 WP	Streptomycin sulfate	Residential use.
87108–1	87108	PDCB Molten Insecticide	Paradichlorobenzene	Bird use.
87108–2	87108	PDCB Flakes	Paradichlorobenzene	Bird use.

Table 3 of this unit includes the names and addresses of record for all the registrants of the products listed in Tables 1 & 2 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in Table 1 and Table 2 of this unit.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION AND/OR AMENDMENTS

EPA company No.	Company name and address
228	NuFarm Americas, Inc., 4020 Aerial Center Pkwy., Ste. 101, Morrisville, NC 27560.
264	Bayer CropScience, LP, 800 N Lindbergh Blvd., St. Louis, MO 63167.
279	FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104.
400	Macdermid Agricultural Solutions, Inc., C/O Arysta Lifescience North America, LLC, Agent Name: UPL NA Inc., 630 Freedom Business Center, #402, King of Prussia, PA 19406.
464	DDP Specialty Electronic Materials US, Inc., 1501 Larkin Center Drive, Midland, MI 48674.
1258	Arch Chemicals, Inc., 1200 Bluegrass Lakes Parkway, Alpharetta, GA 30004.
1381	Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164–0589.
1475	Willert Home Products, Inc., 4044 Park Avenue, St. Louis, MO 63110.
2792	Decco US Post-Harvest, Inc., 1713 South California Avenue, Monrovia, CA 91016–0120.
7313	PPG Architectural Finishes, Inc., Agent Name: PPG Architectural Finishes, Inc., 440 College Park, Monroeville, PA 15146.
7364	Innovative Water Care, LLC, D/B/A GLB Pool & Spa, 1400 Bluegrass Lakes Parkway, Alpharetta, GA 30004.
8660	United Industries Corp., D/B/A Sylorr Plant Corp., P.O. Box 142642, St. Louis, MO 63114–0642.
10163	Gowan Company, P.O. Box 5569, Yuma, AZ 85366.
34688	Akzo Nobel Surface Chemistry, LLC, 525 W Van Buren St., Chicago, IL 60607–3823.
42750	Albaugh, LLC, P.O. Box 2127, Valdosta, GA 31604–2127.
45728	Taminco US, LLC, A Subsidiary of Eastman Chemical Company, 200 S Wilcox Dr., Kingsport, TN 37660–5147.
46923	Old Bridge Chemicals, Inc., Agent Name: Landis International, Inc., 3185 Madison Highway, P.O. Box 5126, Valdosta, GA 31603–5126.
56228	U.S Department of Agriculture, Animal and Plant Health Inspection Service, 4700 River Road, Unit 149, Riverdale, MD 20737.
57787	Haviland Consumer Products, Inc., Agent Name: TSG Consulting, 1150 18th Street NW, Suite 1000, Washington, DC 20036.
62719	Dow Agrosciences, LLC, 9330 Zionsville Rd., 308/2E, Indianapolis, IN 46268–1054.
66222	Makhteshim Agan of North America, Inc., D/B/A Adama, 3120 Highwoods Blvd., Suite 100, Raleigh, NC 27604.
69681	Allchem Performance Products, Inc., 6010 NW First Place, Gainesville, FL 32607.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION AND/OR AMENDMENTS—Continued

EPA company No.	Company name and address
70127	Novozymes Biologicals, Inc., Agent Name: Exponent, Inc., 1150 Conn. Ave. NW, Suite 1100, Washington, DC 20036.
70506	UPL NA, Inc., 630 Freedom Business Center, Suite 402, King of Prussia, PA 19406.
71711	Nichino America, Inc., 4550 Linden Hill Road, Suite 501, Wilmington, DE 19808.
80990	Agrosource, Inc., P.O. Box 3091, Tequesta, FL 33469.
85678	Redeagle International, LLC, Agent Name: Wagner Regulatory Associates, Inc., P.O. Box 640, Hockessin, DE 19707.
87108	Jiangsu Yangnong Chemical Group Co., Ltd., Agent Name: Landis International, Inc., P.O. Box 5126, Valdosta, GA 31603–5126.
87663	Emery Oleochemicals, LLC, 4900 Este Avenue, Cincinnati, OH 45232.
87703	Spectrum Brands Pet Group, Inc., D/B/A United Pet Group, Inc., 3001 Commerce Street, Blacksburg, VA 24060.
88356	Nicca USA, Inc., 1044 S Nelson Dr., Fountain Inn, SC 29644.

III. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the**Federal Register**.

Section 6(f)(1)(B) of FIFRA (7 U.S.C. 136d(f)(1)(B)) requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) (7 U.S.C. 136d(f)(1)(C)) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants listed in Table 3 of Unit II have requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 30-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Requests

Registrants who choose to withdraw a request for product cancellation or use termination should submit the withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation or termination action, the effective date of cancellation or termination and all other provisions of any earlier cancellation or termination action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the action. If the requests for voluntary cancellation and amendments to terminate uses are granted, the Agency intends to publish the cancellation order in the **Federal Register**.

In any order issued in response to these requests for cancellation of product registrations and for amendments to terminate uses, EPA proposes to include the following provisions for the treatment of any existing stocks of the products listed in Table 1 of Unit II.

A. For Products 464–782; 464–8126; 464–8127 & 464–8129

For products 464–782; 464–8126; 464–8127 & 464–8129, listed in Table 1 of Unit II, the registrant has requested 18-months to sell existing stocks. Registrants will be permitted to sell and distribute existing stocks of these products for 18-months after the effective date of the cancellation, which will be the date of publication of the cancellation order in the **Federal Register**. Thereafter, registrants will be prohibited from selling or distributing these products, except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

For all other voluntary product cancellations, identified in Table 1 of Unit II, registrants will be permitted to sell and distribute existing stocks of voluntarily canceled products for 1-year after the effective date of the cancellation, which will be the date of publication of the cancellation order in the **Federal Register**. Thereafter, registrants will be prohibited from selling or distributing all other products identified in Table 1 of Unit II, except for export consistent with FIFRA section 17 (7 U.S.C. 136o) or for proper disposal.

Once EPA has approved product labels reflecting the requested amendments to terminate uses, identified in Table 2 of Unit II, registrants will be permitted to sell or distribute products under the previously approved labeling for a period of 18-months after the date of **Federal Register** publication of the cancellation order, unless other restrictions have been imposed. Thereafter, registrants will be prohibited from selling or distributing the products whose labels include the terminated uses identified in Table 2 of Unit II, except for export consistent with FIFRA section 17 or for proper disposal.

Persons other than the registrant may sell, distribute, or use existing stocks of canceled products and products whose labels include the terminated uses until supplies are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products and terminated uses.

(Authority: 7 U.S.C. 136 *et seq.*)

Dated: October 1, 2019.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2019–23386 Filed 10–24–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1167]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before December 24, 2019. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1167.

Title: Accessible Telecommunications and Advanced Communications Services and Equipment.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households; business or other for-profit entities; not-for-profit institutions.

Number of Respondents and Responses: 3,541 respondents; 42,106 responses.

Estimated Time per Response: .50 hours (30 minutes) to 40 hours.

Frequency of Response: Annual, one time, and on occasion reporting requirements; recordkeeping requirement; third-party disclosure requirement.

Obligation to Respond: Mandatory. Statutory authority for this information collection is contained in sections 1–4, 255, 303(r), 403, 503, 716, 717, and 718 of the Communications Act, as amended, 47 U.S.C. 151–154, 255, 303(r), 403, 503, 617, 618, and 619.

Total Annual Burden: 120,999 hours.

Total Annual Cost: $17,800.

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's system of records notice (SORN), FCC/CGB–1, ''Informal Complaints, Inquiries and Requests for Dispute Assistance,'' which became effective on September 24, 2014. In addition, upon the service of an informal or formal complaint, a service provider or equipment manufacturer must produce to the Commission, upon request, records covered by 47 CFR 14.31(a) of the Commission's rules that are directly relevant to the equipment or service that is the subject of such complaint and may assert a statutory request for confidentiality for these records. All other information submitted to the Commission pursuant to Subpart D of Part 14 of the Commission's rules or to any other request by the Commission may be submitted pursuant to a request for confidentiality in accordance with 47 CFR 0.459 of the Commission's rules.

Privacy Impact Assessment: The FCC completed a Privacy Impact Assessment (PIA) on June 28, 2007. The PIA may be reviewed at *https://www.fcc.gov/general/privacy-act-information.* The FCC is in the process of updating the PIA to incorporate various revisions made to the SORN.

Needs and Uses: In 2011, in document FCC 11–151, the FCC adopted rules to implement sections 716 and 717 of the Communications Act of 1934 (the Act), as amended, which were added to the Act by the Twenty-First Century Communications and Video Accessibility Act of 2010 (CVAA). *See* Public Law 111–260, 104. Section 716 of the Act requires providers of advanced communications services and manufacturers of equipment used for advanced communications services to make their services and equipment accessible to individuals with disabilities, unless doing so is not achievable. 47 U.S.C. 617. Section 717 of the Act established new recordkeeping requirements and enforcement procedures for service providers and equipment manufacturers that are subject to sections 255, 716, and 718 of the Act. 47 U.S.C. 618. Section 255 of the Act requires telecommunications and interconnected VoIP services and equipment to be accessible to individuals with disabilities, if readily achievable. 47 U.S.C. 255. Section 718 of the Act requires internet browsers built into mobile phones to be accessible to and usable by individuals who are blind or have a visual impairment, unless doing so is not achievable. 47 U.S.C. 619.

In document FCC 11–151, the Commission adopted rules relating to the following:

(a) Service providers and equipment manufacturers that are subject to sections 255, 716, and 718 of the Act must ensure that the information and documentation that they provide is accessible to individuals with disabilities.

(b) Service providers and equipment manufacturers may seek waivers from the accessibility obligations of section 716 of the Act for services or equipment that are designed for multiple purposes, including advanced communications services, but are designed primarily for purposes other than using advanced communications services.

(c) Service providers and equipment manufacturers that are subject to sections 255, 716, and 718 of the Act must maintain records of their efforts to implement those sections.

(d) Service providers and equipment manufacturers that are subject to sections 255, 716, and 718 of the Act must certify annually to the Commission that records are kept in accordance with the recordkeeping requirements. The certification must include contact details of the person(s) authorized to resolve accessibility complaints and the agent designated for service of process.

(e) The Commission established procedures to facilitate the filing of formal and informal complaints alleging violations of sections 255, 716, or 718 of the Act. Those procedures include a nondiscretionary pre-filing notice procedure to facilitate dispute resolution, that is, as a prerequisite to filing an informal complaint, complainants must first request dispute assistance from the Consumer and Governmental Affairs Bureau's Disability Rights Office.

In 2013, in document FCC 13–57, the FCC adopted rules to implement section 718 of the Act.

In 2015, in document FCC 15–24, the FCC reclassified broadband internet access service (BIAS) as a telecommunications service that is

subject to the Commission's regulatory authority under Title II of the Act and applying section 255 of the Act and the Commission's implementing rules to providers of BIAS and manufacturers of equipment used for BIAS. In 2017, in document FCC 17–166, the Commission reinstated the information service classification of BIAS. Therefore, the Commission extracted those burdens from the collection found in OMB control number 3060–1167.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–23328 Filed 10–24–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0667 and 3060–1092]

Information Collections Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before November 25, 2019. If you anticipate that you will be submitting comments but find it difficult to do so with the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@OMB.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control Number: 3060–0667.

Title: Section 76.630(a), Compatibility with Consumer Electronic Equipment.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 1 respondent, 50,001 responses.

Estimated Hours per Response: .017–3 hours.

Frequency of Response: On occasion reporting requirement.

Total Annual Burden: 853 hours.

Total Annual Cost: $1,550.

Privacy Impact Assessment: No impact(s).

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in Section 4(i) and Section 632 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The information collection requirements contained in 47 CFR 76.630(a) state a cable system operator shall not scramble or otherwise encrypt signals carried on the basic service tier. Requests for waivers of this prohibition must demonstrate either a substantial problem with theft of basic tier service or a strong need to scramble basic signals for other reasons. As part of this showing, cable operators are required to notify subscribers by mail of waiver requests. The notice to subscribers must be mailed no later than thirty calendar days from the date the request waiver was filed with the Commission, and cable operators must inform the Commission in writing, as soon as possible, of that notification date. The notification to subscribers must state: On (date of waiver request was filed with the Commission), (cable operator's name) filed with the Federal Communications Commission a request for waiver of the rule prohibiting scrambling of channels on the basic tier of service. 47 CFR 76.630(a). The request for waiver states (a brief summary of the waiver request). A copy of the request for waiver is on file for public inspection at (the address of the cable operator's local place of business).

Individuals who wish to comment on this request for waiver should mail comments to the Federal Communications Commission by no later than 30 days from (the date the notification was mailed to subscribers). Those comments should be addressed to the: Federal Communications Commission, Media Bureau, Washington, DC 20554, and should include the name of the cable operator to whom the comments are applicable. Individuals should also send a copy of their comments to (the cable operator at its local place of business). Cable operators may file comments in reply no

later than 7 days from the date subscriber comments must be filed.

OMB Control Number: 3060–1092.

Title: Interim Procedures for Filing Applications Seeking Approval for Designated Entity Reportable Eligibility Events and Annual Reports.

Form Numbers: FCC Forms 609–T and 611–T.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for profit institutions; and State, Local and Tribal Governments.

Number of Respondents: 1,100 respondents; 2,750 responses.

Estimated Time per Response: .50 hours to 6 hours.

Frequency of Response: On occasion and annual reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 4(i), 308(b), 309(j)(3) and 309(j)(4).

Total Annual Burden: 7,288 hours.

Total Annual Cost: $2,223,375.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In general, there is no need for confidentiality. On a case by case basis, the Commission may be required to withhold from disclosure certain information about the location, character, or ownership of a historic property, including traditional religious sites.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this comment period to obtain the three year clearance from them. FCC Form 609–T is used by Designated Entities (DEs) to request prior Commission approval pursuant to Section 1.2114 of the Commission's rules for any reportable eligibility event. The data collected on the form is used by the FCC to determine whether the public interest would be served by the approval of the reportable eligibility event.

FCC Form 611–T is used by DE licensees to file an annual report, pursuant to Section 1.2110(n) of the Commission's rules, related to eligibility for designated entity benefits.

The information collected will be used to ensure that only legitimate small businesses reap the benefits of the Commission's designated entity program. Further, this information will assist the Commission in preventing companies from circumventing the objectives of the designated entity eligibility rules by allowing us to review: (1) The FCC 609–T applications seeking approval for ''reportable eligibility events'' and (2) the FCC Form 611–T annual reports to ensure that licensees receiving designated entity benefits are in compliance with the Commission's policies and rules.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–23332 Filed 10–24–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0678]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before December 24, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at 202–418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0678.

Title: Part 25 of the Commission's Rules Governing the Licensing of, and Spectrum Usage by, Satellite Network Stations and Space Stations.

Form No: FCC Form 312, FCC Form 312–EZ, FCC Form 312–R and Schedules A, B and S.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities and Not-for-profit institutions.

Number of Respondents: 6,524 respondents; 6,573 responses.

Estimated Time per Response: 0.5–80 hours.

Frequency of Response: On occasion, one time, and annual reporting requirements; third-party disclosure requirement; recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The Commission has statutory authority for the information collection requirements under 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605, and 721.

Total Annual Burden: 44,992 hours.

Total Annual Cost: $16,612,586.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality pertaining to the information collection requirements in this collection.

Needs and Uses: On August 2, 2019, the Commission released a Report and Order, FCC 19–81, in IB Docket No. 18–86, titled ''Streamlining Licensing Procedures for Small Satellites'' (Small Satellite Report and Order). In this Report and Order, the Commission adopted a new alternative, optional licensing process for small satellites and spacecraft, called the ''Part 25 streamlined small satellite process.'' This new process allows qualifying applicants for small satellites and spacecraft to take advantage of an easier application process, a lower application fee, and a shorter timeline for review than currently exists for applicants under the Commission's existing Part 25 satellite licensing rules. The Commission limited the regulatory burdens borne by applicants, while promoting orbital debris mitigation and

efficient use of spectrum. The Commission's action supports and encourages the increasing innovation in the small satellite sector and helps to preserve U.S. leadership in space-based services and operations. This information collection will provide the Commission and the public with necessary information about the operations of this growing area of satellite operations. While this information collection represents an overall increase in the burden hours, the increase is due to an anticipated overall increase in number of applications as a result of additional applications being filed under the streamlined process adopted in the Small Satellite Report and Order. This information collection represents a decrease in the paperwork burdens for individual operators of non-geostationary orbit (NGSO) satellites who may now qualify for streamlined processing as small satellites, and serves the public interest by streamlining the collection of information and allowing the Commission to authorize small satellites and spacecraft under the new process established in the Report and Order.

Specifically, FCC 19–81 contains new or modified information collection requirements listed below:

(1) Space station application requirements for qualifying small satellites and small spacecraft have been specified in new sections 25.122 and 25.123, respectively. These new sections, including the certifications, incorporate some existing information requirements from other sections, but eliminate the need for small satellite and spacecraft applicants to provide much of the information that part 25 space station applicants would typically be required to provide in narrative format under section 25.114(d). The new or modified informational requirements in sections 25.122 and 25.123 are listed as follows:

a. For small satellite applications filed under section 25.122, a certification that the space stations will operate in non-geostationary orbit, or for small spacecraft applications filed under section 25.123, a certification that the space station(s) will operate and be disposed of beyond Earth's orbit.

b. A certification that the total in-orbit lifetime for any individual space station will be six years or less.

c. For small satellite applications filed under 25.122, a certification that the space station(s) will either be deployed at an orbital altitude of 600 km or below, or will maintain a propulsions system and have the ability to make collision avoidance and deorbit maneuvers using propulsion. This certification will not apply to small spacecraft applications filed under section 25.123.

d. A certification that each space station will be identifiable by a unique signal-based telemetry marker distinguishing it from other space stations or space objects.

e. A certification that the space station(s) will release no operational debris.

f. A certification that the space station operator has assessed and limited the probability of accidental explosions resulting from the conversion of energy sources on board the space station(s) into energy that fragments the spacecraft.

g. A certification that the probability of a collision between each space station and any other large object (10 centimeters or larger) during the orbital lifetime of the space station is 0.001 or less as calculated using current NASA software or other higher fidelity model.

h. For small satellite applications filed under section 25.122, a certification that the space station(s) will be disposed of through atmospheric re-entry, and that the probability of human casualty from portions of the spacecraft surviving re-entry and reaching the surface of the Earth is zero as calculated using current NASA software or higher fidelity models. This certification will not apply to small spacecraft applications filed under section 25.123.

i. A certification that operations of the space station(s) will be compatible with existing operations in the authorized frequency band(s) and will not materially constrain future space station entrants from using the authorized frequency bands.

j. A certification that the space station(s) can be commanded by command originating from the ground to immediately cease transmissions and the licensee will have the capability to eliminate harmful interference when required under the terms of the license or other applicable regulations.

k. A certification that each space station is 10 cm or larger in its smallest dimension.

l. For small satellite applications filed under section 25.122, a certification that each space station will have a mass of 180 kg or less, including any propellant. For small spacecraft applications filed under section 25.123, a certification that each space station will have a mass of 500 kg of less, including any propellant.

m. A description of means by which requested spectrum could be shared with both current and future operators (*e.g.,* how ephemeris data will be shared, antenna design, earth station geographic locations) thereby not materially constraining other operations in the requested frequency bands.

n. For space stations with any means of maneuverability, including both active and passive means, a description of the design and operation of maneuverability and deorbit systems, and a description of the anticipated evolution over time of the orbit of the proposed satellite or satellites.

o. In any instances where spacecraft capable of having crew aboard will be located at or below the deployment orbital altitude of the space station seeking a license, a description of the design and operational strategies that will be used to avoid in-orbit collision with such crewed spacecraft shall be furnished at the time of application. This narrative requirement will not apply to space stations that will operate beyond Earth's orbit.

p. A list of the FCC file numbers or call signs for any known applications or Commission grants related to the proposed operations (*e.g.,* experimental license grants, other space station or earth station applications or grants).

(2) The informational requirements listed in section 25.137 for requests for U.S.-market access through non-U.S.-licensed space stations were also modified to refer to sections 25.122 and 25.123, for those applicants seeking U.S. market access under the small satellite or spacecraft process.

This collection is also used by staff in carrying out United States treaty obligations under the World Trade Organization (WTO) Basic Telecom Agreement. The information collected is used for the practical and necessary purposes of assessing the legal, technical, and other qualifications of applicants; determining compliance by applicants, licensees, and other grantees with Commission rules and the terms and conditions of their grants; and concluding whether, and under what conditions, grant of an authorization will serve the public interest, convenience, and necessity.

As technology advances and new spectrum is allocated for satellite use, applicants for satellite service will continue to submit the information required in 47 CFR part 25 of the Commission's rules. Without such information, the Commission could not determine whether to permit respondents to provide telecommunication services in the United States. Therefore, the Commission would be unable to fulfill its statutory responsibilities in accordance with the Communications Act of 1934, as amended, and the

obligations imposed on parties to the WTO Basic Telecom Agreement.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–23333 Filed 10–24–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1095]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before December 24, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at 202–418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–1095.

Title: Surrenders of Authorizations for International Carrier, Space Station and Earth Station Licensees.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 8 respondents; 8 responses.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Voluntary. The statutory authority for this information collection is contained in Sections 4(i), 7(a), 11, 303(c), 303(f), 303(g), and 303(r) of the Communications Act of 1934, as amended; 47 U.S.C. 154(i), 157(a), 161, 303(c), 303(f), 303(g), and 303(r).

Total Annual Burden: 8 hours.

Annual Cost Burden: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: In general, there is no need for confidentiality with is collection of information.

Needs and Uses: This collection will be submitted to the Office of Management and Budget (OMB) as an extension after this 60-day comment period has ended in order to obtain the full three-year clearance from OMB. There are no changes in the number of respondents, responses, annual burden hours and total annual costs.

Licensees file surrenders of authorizations with the Commission on a voluntary basis. This information is used by Commission staff to issue Public Notices to announce the surrenders of authorization to the general public. The Commission's release of Public Notices is critical to keeping the general public abreast of the licensees' discontinuance of telecommunications services.

Without this collection of information, licensees would be required to submit surrenders of authorizations to the Commission by letter which is more time consuming than submitting such requests to the Commission electronically. In addition, Commission staff would spend an extensive amount of time processing surrenders of authorizations received by *43013 letter. The collection of information saves time for both licensees and Commission staff since they are received in IBFS electronically and include only the information that is essential to process the requests in a timely manner. Furthermore, the E-filing module expedites the Commission staff's announcement of surrenders of authorizations via Public Notice.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–23331 Filed 10–24–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1264]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before December 24, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1264.

Title: Application to Participate in a Toll Free Number Auction, FCC Form 833.

Form Number: FCC Form 833.

Type of Review: Extension of a currently approved information collection.

Respondents: Business or other for-profit entities, Individuals or households, Not-for-profit institutions, Federal Government, State, Local or Tribal Governments.

Number of Respondents and Responses: 200 respondents; 200 responses.

Estimated Time per Response: 1.5 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection is contained in sections 1, 4(i), 201(b) and 251(e)(1) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 201(b), 251(e)(1).

Total Annual Burden: 300 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: The Commission will determine if a Privacy Impact Assessment is required.

Nature and Extent of Confidentiality: Information collected on FCC Form 833 is made available for public inspection, and the Commission is not requesting that respondents submit confidential information as part of the pre-auction application process. For individuals, the Privacy Act, 5 U.S.C. 552a, is the statutory authority for confidentiality and applies to this information collection. To the extent the information submitted pursuant to this information collection is determined to be confidential, it will be protected by the Commission. If a respondent seeks to have certain information collected on FCC Form 833 withheld from public inspection, the respondent may request confidential treatment of such information pursuant to section 0.459 of the Commission's rules. *See* 47 CFR 0.459.

Needs and Uses: The Commission's rules and related requirements are designed to ensure that the competitive bidding process for assigning toll free numbers is limited to qualified applicants, deter possible abuse of the bidding process, and enhance the use of competitive bidding to assign toll free numbers in furtherance of the public interest. Applicants will use FCC Form 833 to submit the required disclosures and certifications, and the information collected on FCC Form 833 will then be reviewed to determine if an applicant is qualified to bid in a toll free number auction. Toll free number auctions will not be able to occur without the collection of information on FCC Form 833. Without the information collected on FCC Form 833, a determination of whether the applicant is qualified to bid in a toll free number auction cannot be made.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–23330 Filed 10–24–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1005]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before December 24, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1005.

Title: Numbering Resource Optimization—Phase 3.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit and State, Local, or Tribal Government.

Number of Respondents and Responses: 17 respondents; 32 responses.

Estimated Time per Response: 40–50 hours.

Frequency of Response: On occasion reporting requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 153, 154, 201–205, 207–209, 218, 225–227, 251–252, 271, and 332.

Total Annual Burden: 830 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission is not requesting that respondents submit confidential information to the Commission. If the Commission requests respondents to submit information which respondents believe is confidential, respondents may request confidential treatment of such information pursuant to 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission established a safety valve to ensure that

carriers experiencing rapid growth in a given market will be able to meet customer demand. States may use this safety valve to grant requests from carriers that demonstrate the following:

(1) The carrier will exhaust its numbering resources in a market or rate area within three months (in lieu of six months-to-exhaust requirement); and

(2) Projected growth is based on the carrier's actual growth in the market or rate area, or in the carrier's actual growth in a reasonably comparable market, but only if that projected growth varies no more than 15 percent from historical growth in the relevant market.

The Commission lifted the ban on service-specific and technology-specific overlays (collectively, specialized overlays or SOs), allowing state commissions seeking to implement SOs to request delegated authority to do so on a case-by-case basis. To provide further guidance to state commissions, the Commission set forth the criteria that each request for delegated authority to implement a SO should address. This will enable us to examine the feasibility of SOs in a particular area, and to determine whether the Commission's stated goals are likely to be met if the SO is implemented. Specifically, state commissions should also specifically address the following:

(1) The technologies or services to be included in the SO;

(2) The geographic area to be covered;

(3) Whether the SO will be transitional;

(4) When the SO will be implemented and, if a transitional SO is proposed, when the SO will become an all-services overlay;

(5) Whether the SO will include take-backs;

(6) Whether there will be 10-digit dialing in the SO and the underlying area code(s);

(7) Whether the SO and underlying area code(s) will be subject to rationing; and

(8) Whether the SO will cover an area in which pooling is taking place.

The Commission uses the information it collects to assist the state commissions in carrying out their delegated authority over numbering resources.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2019–23329 Filed 10–24–19; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, with revision, the Intermittent Survey of Businesses (FR 1374; OMB No. 7100–0302).

DATES: Comments must be submitted on or before December 24, 2019.

ADDRESSES: You may submit comments, identified by FR 1374, by any of the following methods:

- *Agency Website: https://www.federalreserve.gov/.* Follow the instructions for submitting comments at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include the OMB number in the subject line of the message.
- *Fax:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *https://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room 146, 1709 New York Avenue NW, Washington, DC 20006, between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the Paperwork Reduction Act (PRA) OMB submission, including the reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, if approved. These documents will also be made available on the Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears below.

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;

b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, With Revision, the Following Information Collection

Report title: Intermittent Survey of Businesses.

Agency form number: FR 1374.

OMB control number: 7100–0302.

Frequency: On occasion.

Respondents: Businesses and state and local governments.

Estimated number of respondents: 720.

Estimated average hours per response: 15 minutes.

Estimated annual burden hours: 540.

General description of report: The survey data are used to gather information specifically tailored to the Federal Reserve's policy and operational responsibilities. Currently, this event-generated survey is approved to operate in two ways. First, under the guidance of Board staff, the Reserve Banks survey business contacts as economic developments warrant. Although each survey is contemplated to have approximately 2,400 business respondents (about 200 respondents per Reserve Bank), surveys in recent years have had far fewer respondents; occasionally, state and local government officials are surveyed rather than business, in which case there are also far fewer respondents. It is necessary to conduct these surveys to provide timely information to the members of the Board and presidents of the Reserve Banks. Usually, these surveys are conducted by Reserve Bank economists telephoning or emailing purchasing managers, economists, or other knowledgeable individuals at selected, relevant businesses. Reserve Bank staff may also use online survey tools to collect responses to the survey. The frequency and content of the questions, as well as the entities contacted, vary depending on developments in the economy. The draft reporting form provides a sample of the types of questions used in a previous survey to illustrate the format of these surveys. Second, economists at the Board survey business contacts by telephone, inquiring about current business conditions. Board economists conduct these surveys as economic conditions require, with approximately ten respondents for each survey.

Proposed revisions: For surveys conducted by the Reserve Banks at the direction of the Board, the Board proposes to decrease the number of respondents from 2,400 to 720 (an average of 60 per Reserve Bank). This decrease better reflects the actual number of respondents in recent years. In addition, the Board proposes to discontinue the surveys conducted solely by the Board, as they have not been conducted in recent years and are not anticipated to be needed in the future.

Legal authorization and confidentiality: The FR 1374 is authorized by sections 2A and 12A of the Federal Reserve Act (FRA). Section 2A of the FRA requires that the Board and the Federal Open Market Committee (FOMC) ''maintain long run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates.'' [1] Under section 12A of the FRA, the FOMC is required to implement regulations relating to the open market operations conducted by Federal Reserve Banks ''with a view to accommodating commerce and business and with regard to their bearing upon the general credit situation of the country.'' [2] In order to carry out these objectives, the Board must collect economic data, including by using the FR 1374. Survey submissions are voluntary.

Individual respondents may request that information submitted to the Board through a survey under FR 1374 be kept confidential. If a respondent requests confidential treatment, the Board will determine whether the information is entitled to confidential treatment on a case-by-case basis. The Board will consider whether information collected through these surveys may be kept confidential under exemption [4] for the Freedom of Information Act (''FOIA''), which protects privileged or confidential commercial or financial information,[3] or any other applicable FOIA exemption.

Board of Governors of the Federal Reserve System, October 22, 2019.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2019–23321 Filed 10–24–19; 8:45 am]

BILLING CODE 6210–01–P

[1] 12 U.S.C. 225a.

[2] 12 U.S.C. 263(c).

[3] 5 U.S.C. 552(b)(4).

FEDERAL TRADE COMMISSION

[File No. 192 3008]

Sunday Riley Modern Skincare, LLC; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before November 25, 2019.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: ''Sunday Riley Modern Skincare, LLC; File No. 192 3008'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Michael Ostheimer (202–326–2699), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for October 21, 2019), on the World Wide Web, at *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before November 25, 2019. Write ''Sunday Riley Modern Skincare, LLC; File No. 192 3008'' on your comment. Your comment—including your name and your state—will be placed on the

public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Sunday Riley Modern Skincare, LLC; File No. 192 3008'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before November 25, 2019. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing a consent order from Sunday Riley Modern Skincare, LLC (''Sunday Riley Skincare'') and its Chief Executive Officer, Ms. Sunday Riley (collectively ''respondents'').

The proposed consent order (''order'') has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves the respondents' marketing of their Sunday Riley brand cosmetic products. The respondents have sold their cosmetic products through Sephora's website, *www.sephora.com,* which provides consumers the opportunity to leave product reviews. According to the complaint, on multiple occasions, Sunday Riley Skincare managers, including Ms. Riley, posted reviews of Sunday Riley brand cosmetic products on the Sephora website using fake accounts created just for that purpose or requested that other employees do so. The complaint alleges that the respondents violated Section 5(a) of the FTC Act by misrepresenting that certain reviews of Sunday Riley brand products on the Sephora website reflected the independent experiences or opinions of impartial ordinary users of the products, when they were written by Ms. Riley and her employees. The complaint further alleges that the respondents deceptively failed to disclose that certain online consumer reviews were written by Ms. Riley or her employees.

The order contains provisions designed to prevent the respondents from engaging in similar acts and practices in the future.

Provision I prohibits the respondents, in connection with the sale of any product, from misrepresenting the status of any endorser or person providing a review of the product, including misrepresenting that the endorser or reviewer is an independent or ordinary user of the product.

Provision II prohibits the respondents from making any representation about any consumer or other endorser of a product without disclosing, clearly and conspicuously, and in close proximity to that representation, any unexpected material connection between the consumer or endorser and (1) any respondent, or (2) any other individual or entity affiliated with the product. The order defines the terms ''clearly and conspicuously,'' ''close proximity,'' and ''unexpected material connection.''

Provision III requires that the respondents instruct their employees, officers, and agents as to their responsibilities for disclosing their connections to any respondent's product they endorse and that the respondents obtain signed acknowledgements from them. Provision IV mandates that the respondents acknowledge receipt of the order, distribute the order to principals, officers, and certain employees and agents, and obtain signed acknowledgments from them. Provision V requires that the respondents submit compliance reports to the FTC one year after the order's issuance and submit notifications when certain events occur. Provision VI requires the respondents to create certain records for twenty years and retain them for five years. Provision VII provides for the FTC's continued compliance monitoring of the respondents' activity during the order's effective dates. Provision VIII provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint

or order, or to modify the order's terms in any way.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

[FR Doc. 2019–23263 Filed 10–24–19; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–0943; Docket No. CDC–2019–0090]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Data Collection for the Residential Care Community and Adult Day Services Center Components of the National Post-Acute and Long-Term Care Study. The purpose is to collect data for the residential care community and adult day services center components for the 2020 wave of the National Post-Acute and Long-Term Care Study (formerly the National Study of Long-Term Care Providers).

DATES: CDC must receive written comments on or before December 24, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0090 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

The Residential Care Community and Adult Day Service Center components of the National Post-Acute and Long-Term Care Study (OMB Control No. 0920–0943 Exp. 03/12/2019)—Reinstatement with Change—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, ''shall collect statistics on health resources . . . [and] utilization of health care, including extended care facilities, and other institutions.'' NCHS seeks approval to collect data for the Residential Care Community (RCC) and Adult Day Services Center (ADSC) survey components of the 5th National Post-Acute and Long-Term Care Study or NPALS (formerly known as the National Study of Long-Term Care Providers or NSLTCP). A two year clearance is requested.

The NPALS is designed to (1) broaden NCHS' ongoing coverage of paid, regulated long-term care (LTC) providers; (2) merge with existing administrative data on LTC providers and service users (*i.e.,* Centers for Medicare and Medicaid Services (CMS) data on inpatient rehabilitation facilities and patients, long-term care hospitals and patients, nursing homes and residents, home health agencies and patients, and hospices and patients); (3) update data more frequently on LTC providers and service users for which nationally representative administrative data do not exist; and (4) enable comparisons across LTC sectors and timely monitoring of supply and use of these sectors over time.

Data will be collected from two types of LTC providers in the 50 states and the District of Columbia: 11,600 RCCs and 5,500 ADSCs in each wave. Data were collected in 2012, 2014, 2016, and 2018. The data to be collected in 2020 include the basic characteristics, services, staffing, and practices of RCCs and ADSCs, and aggregate-level distributions of the demographics, selected health conditions and health care utilization, physical functioning, and cognitive functioning of RCC residents and ADSC participants.

Expected users of data from this collection effort include, but are not limited to CDC; other Department of Health and Human Services (DHHS) agencies, such as the Office of the Assistant Secretary for Planning and Evaluation, The Administration for Community Living, and the Agency for Healthcare Research and Quality; associations, such as LeadingAge, National Center for Assisted Living, American Seniors Housing Association, Argentum, and National Adult Day

Services Association; universities; foundations; and other private sector organizations such as the Alzheimer's Association, the AARP Public Policy Institute, and the National Academies of Sciences, Engineering, and Medicine.

Expected burden from data collection for eligible cases is 30 minutes per respondent, except small RCCs that will have an additional five minutes for a contact confirmation call. We calculated the burden based on a 100% response rate. Two-year clearance is requested to cover the collection of data. The estimated annual burden hours for the collection are 4,534. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Small RCC Director/Designated Staff Member.	Contact Confirmation Call	3,100	1	5/60	258
RCC Director/Designated Staff Member.	RCC Questionnaire Version A	2,900	1	30/60	1,450
RCC Director/Designated Staff Member.	RCC Questionnaire Version B	2,900	1	30/60	1,450
ADSC Director/Designated Staff Member.	ADSC Questionnaire Version A	1,375	1	30/60	688
ADSC Director/Designated Staff Member.	ADSC Questionnaire Version B	1,375	1	30/60	688
Total					4,534

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–23368 Filed 10–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–1072; Docket No. CDC–2019–0091]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled ''*The Enhanced STD surveillance Network (SSuN)*'', which is the only source for enhanced and sentinel STD surveillance data in the United States that serves to strengthen national and local surveillance capacity, collects information on populations at risk for STDs attending healthcare facilities, and provides more accurate estimates of the burden of disease, incidence of disease, trends and impact of STDs at the population level.

DATES: CDC must receive written comments on or before December 24, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0091 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

The Enhanced STD surveillance Network (SSuN), (OMB Control No. 0920–1072, Exp. 09/30/2021)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention is requesting revision of the information collection entitled ''Enhanced STD Surveillance Network (SSuN)''. Revisions to this submission include adding reported adult syphilis cases to enhanced case-based surveillance records, addition of 87 new data elements, removal of 115 data elements associated with a discontinued neurosyphilis surveillance activity, and revision of methods to include Health Department surveillance HIV registry matching activities for patients presenting for care in STD clinical facilities. This revision also includes changes to the number and identity of collaborating jurisdictions from 10 to 11 sites as a result of a recent notice of funding opportunity. The estimate of annualized burden hours for this data collection increases modestly from 3,479 hours to 6,303 hours for the revised project as a result of revisions and expanding the project from 10 to 11 awardees for the current data collection cycle.

The purpose of this project is to enhance capacity for STD surveillance and better meet CDC's disease surveillance mandate by; (1) providing more comprehensive information on reported cases of notifiable STDs to enhance the ability of public health authorities to interpret trends in case incidence, assess inequalities in the burden of disease by population characteristics and to monitor STD treatment and selected adverse health outcomes of STDs, and (2) monitoring STD and HIV co-infection, screening, uptake of high-impact HIV prevention and health care access trends among patients seeking care and those diagnosed with STDs in specific clinical settings.

Routine STD surveillance activities are ongoing in all US states and jurisdictions, and cases are reported to CDC through the National Notifiable Disease Surveillance System (NNDSS). However, case reports are often missing critical patient demographics and are of limited scope with respect to risk behavior, provider and clinical information, treatment, co-infection and partner characteristics—data that are needed to appropriately direct disease control activities. Enhanced SSuN is the only current surveillance infrastructure providing information on patient and partner characteristics, clinical presentation, screening and uptake of HIV testing, treatment patterns, provider compliance with treatment recommendations, HIV co-infection among persons diagnosed with STDs and use of high impact STD-related HIV prevention interventions such as pre-exposure prophylaxis.

The precursor to Enhanced SSuN was the STD Surveillance Network (SSuN), which was established in 2005 as a network of six collaborating state and local public health agencies providing more comprehensive STD case-level and clinical facility information. In 2008, SSuN was expanded to 12 awardees to add important geographic diversity and to include visit-level data on a full census of patients being seen in categorical STD clinics. Activities of the previously funded SSuN were subsumed under the network's scope in establishing enhanced SSuN in 2013, which funded 10 awardees to conduct core data collection activities.

The revised project, SSuN—Cycle 4, comprises 11 US local/state health departments, including Baltimore City Health Department, California Department of Public Health, City of Columbus Public Health Department, Florida Department of Health, Indiana Department of Public Health, Multnomah County Health Department, New York City Department of Health & Mental Hygiene, Philadelphia Department of Public Health, San Francisco Department of Public Health, Utah Department of Public Health and Washington State Department of Health.

Subsequent to reinstatement of OMB approval in 2018, enhanced SSuN continues to provide ongoing data addressing CDC's Division of Sexually Transmitted Disease and Prevention priorities (DSTDP), including contributing to CDC's annual STD surveillance report, CDC's quarterly and annual progress indicators, and has informed policy discussions on expedited partner therapy, pre-exposure prophylaxis to prevent HIV infection (PrEP), documented critical clinical services provided by categorical STD clinics, and provided information on the proportion of cases treated with appropriate antimicrobial regimens, which is an essential indicator of compliance with CDC treatment recommendations and critical for addressing the emergence of antimicrobial resistance. The major data collection components of the network are grouped into two primary strategies, reflecting different sentinel and enhanced population-based surveillance methods.

The first, Strategy A, includes sentinel surveillance in STD clinics to monitor patient care, screening and diagnostic practices, HIV co-infection, treatment and assess the delivery of high impact, STD-related HIV prevention services. Participating local/state health departments are implementing common protocols to abstract demographic, clinical, risk behaviors from existing health records for patients presenting for care in 15 selected local STD Clinics. Data for this strategy is abstracted from existing electronic medical records at the participating STD clinics, leveraging information that is routinely collected in the provision of clinical care. A brief 10-item de-identified survey will be administered at registration to 350 patients presenting consecutively to the clinics once annually to assess demographics not collected in the course of routine patient care. All survey and medical records are fully de-identified by collaborating health departments and transmitted to CDC through secure file transport mechanisms six times annually (every two months). The estimated time for the STD clinic data managers to abstract data from electronic health records and process patient surveys is four hours every two months.

The second surveillance activity in SSuN—Cycle 4, Strategy B, includes abstraction of all reported gonorrhea and adult syphilis cases from the jurisdiction's routine STD surveillance data management system, recoding case data to conform with common protocols and performance of a registry match with the jurisdictions HIV case surveillance system. A random sample of gonorrhea cases is selected, and enhanced investigations conducted on the gonorrhea cases selected in the random sample. Enhanced investigations include clinical data collection from reporting providers, searching existing health department disease and laboratory registries for additional diagnostic and laboratory data, and attempting to obtain brief patient behavioral and demographic interviews on patients selected in the random sample. Estimated time for patients to complete these interviews is 10 minutes or less depending on skip patterns. For these activities, jurisdictions follow consensus protocols for all data collection to provide uniformly coded data on demographic characteristics, behavioral risk factors, clinical care, laboratory data and health care seeking behaviors.

There were 164,177 cases of gonorrhea diagnosed and reported across the 10 participating enhanced SSuN jurisdictions funded in 2018. Approximately 10.6%, or 17,512 cases were randomly sampled for enhanced investigation and full enhanced investigations were completed for 7,132 (40.7%). The remaining cases were lost to follow-up due to insufficient contact information, or the patient failed to respond to multiple contact attempts. Similar performance is anticipated in the revised project, which includes eleven jurisdictions which reported 173,605 gonorrhea cases in 2017. Approximately 17,360 cases will be sampled and 7,380 completed patient investigations are anticipated.

Data managers at each of the 11 local/state health departments are responsible for transmitting validated datasets to CDC every month, alternating between strategies A and B each month. This reflects 3,168 burden hours for data management (11 respondents × 12 data transmissions × 24 hours). Data managers will also be responsible for conducting HIV registry matching bimonthly; registry matches are estimated to take 20 hours for matching, cleaning and recoding records into approved data formats. Across all 11 jurisdictions, this represents an additional data management burden of 1,320 hours (11 sites × 6 annual matches × 20 hours).

The estimated annual burden hours for data management staff in funded jurisdiction is 4,488 hours (3,168 + 1,320) for the revised information collection. Respondents from local/state health departments receive federal funds to participate in this project. Participation of patients and of facility staff is voluntary. The total estimated annual burden hours for which CDC seeks approval is 6,303. There are no additional costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Data managers at sentinel STD clinics.	Electronic Clinical Record Abstraction.	11	6	4	264
General Public—Adults (persons diagnosed with gonorrhea).	Patient interviews for a random sample of gonorrhea cases.	7,380	1	10/60	1,230
Data Managers: 11 local/state health department.	Data cleaning/validation, HIV registry matching and data transmission for Strategy A and Strategy B.	11	12	44	4,488
General Public—Adults (persons visiting STD clinics and participating in the clinic survey).	Clinic Survey	3850	1	5/60	321
Total		11,274			6,303

Jeffery Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–23369 Filed 10–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–19ARD]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Evaluation of CDC's STEADI Older Adult Fall Prevention Initiative in a Primary Care Setting'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on May 24, 2019, to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

An Evaluation of CDC's STEADI Older Adult Fall Prevention Initiative in a Primary Care Setting—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Falls are the leading cause of both fatal and non-fatal injuries among older adults, defined as age 65 and older.

From 2007 to 2016, fall death age-adjusted rates increased by 31% with almost 30,000 older adults dying as the result of a fall in 2016. The economic consequences of falls are significant and growing as the population ages, with medical costs of older adult falls estimated at $50 billion. CDC created the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative to guide health care providers' fall prevention activities in the primary care setting.

This new data collection effort is an essential component to determine the impact of CDC's Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative on falls, emergency department visits, and hospitalizations due to falls. It will help CDC determine the impact of less resource intense versions of STEADI and evaluate the process of implementing STEADI fall prevention initiative in a primary care setting to provide context for the impact evaluations. The study population will be limited to adults 65 and older who have an outpatient visit during the study period and screen as high risk for falls at the selected primary care clinics implementing the STEADI fall prevention initiative. The study population for the process evaluation will include the clinical implementation staff at the selected clinics where the intervention will take place (physicians, physician assistants/nurse practitioners, study research nurses, and practice or operations manager).

Two data collection methods will be used; the CDC's Stay Independent Fall Risk Screener will be administered to older adult patients at selected primary care clinics to determine which older adults are at high risk for a fall. Those who screen at high risk will be assigned, based on clinic attended and week of attendance, to one of three study arms. Patient surveys will be used to determine whether these patients experience a fall during the study period, are treated for a fall, and/or use any fall prevention strategies throughout the study period. Four surveys will be administered to each patient during a 12-month period: One baseline survey and three follow-up surveys. Older adults will also be asked to keep track of their falls in a monthly falls diary, so they can accurately recall and report the information during the 12-month period for the patient surveys. The process evaluation interviews will be used to understand the attitudes of clinical staff towards the implementation process, barriers and facilitators to implementation, and the implementation fidelity to core components of the STEADI initiative. Descriptive statistics and cross tabulations will be used to describe quantitative data from the patient survey and process evaluation data. Risk ratios of the effect of the intervention on post-intervention falls will be calculated comparing intervention and control groups while controlling for demographic, health, attitude, and behavior variables.

The data collected from this study will be used to demonstrate the impact of STEADI and different components of STEADI on falls and fall injuries in a primary care setting, and improve the implementation of STEADI in a primary care setting. There are no costs to the respondents other than their time. The total estimated annualized burden is 1,578 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (hours)
Patient	Stay Independent Fall Risk Screener (Att. D)	4,035	1	6/60
	Consent Form (Att. C)	1,235	1	12/60
	Patient Baseline Survey (Att. B1)	1,000	1	15/60
	Patient Follow-up Survey (Att. B2)	896	3	15/60
Physician/Physician Assistants/Nurse Practitioners.	Provider Interview Guide/Consent (Att. E1)	3	1	50/60
Clinic Operations Manager	Operations Manager Interview Guide/Consent (Att. E2).	2	1	50/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–23365 Filed 10–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–20–1158; Docket No. CDC–2019–0095]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled CDC Ideation Catalyst (I-Catalyst) Program and Customer Engagement Information Collection. CDC will collect qualitative information from potential customers and other stakeholders about their needs and preferred approaches to solving public health problems. Findings will be used to improve customer satisfaction with, and usability of, CDC's products, programs, and services.

DATES: CDC must receive written comments on or before December 24, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0095 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without

change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

CDC Ideation Catalyst (I-Catalyst) Program and Customer Engagement Information Collection (OMB Control No. 0920–1158, Exp. 1/31/2020)—Revision—Office of Science (OS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC Office of Technology and Innovation (OTI) within Office of Science (OS) fosters innovative science and promotes the testing and implementation of innovative ideas that improve CDC's ability to have public health impact. To arm CDC staff with an expanded skill-set and tools to evaluate and translate their insights and ideas into solutions, CDC developed an experiential innovation curriculum called Ideation Catalyst (I-Catalyst). The program was created with the belief that innovation should be customer-driven, be based on user research, and is something people at all levels of an organization can engage in. CDC also obtained OMB approval for a generic clearance to support the collection of information from stakeholders and customers, utilizing I-Catalyst program principles and methodology (CDC I-Catalyst Program, OMB Control No. 0920–1158, Exp. date 1/31/2020).

The goal of the I-Catalyst program is to help CDC employees test and explore their ideas through a discovery, ideation, and prototyping process. I-Catalyst offers a process for defining problems and developing strategies to solutions that will help improve the quality and efficiency of innovation efforts and, as a result, overall performance. Through the I-Catalyst Program, teams work to define and articulate their problem space to find effective solutions and CDC programs receive consultation from OTI staff to implement the I-Catalyst process with specific projects. Participating teams will go through a hypothesis-testing, scientific method of discovery to gather important insights and identify issues associated with their projects. Teams are forced ''out of the classroom'' to conduct interviews, study customer/stakeholder needs, collect feedback, and find partnership opportunities. It is expected that participants will gain the ability to evaluate and translate their insights into solutions.

The I-Catalyst process provides CDC staff with real-world, hands-on entrepreneurship training and consultation from OTI staff. Through I-Catalyst, CDC staff make hypotheses about how the world works, and then test them by getting out of the building and talking to customers and/or stakeholders. Only conversations with potential customers/stakeholders can provide the facts from which hypotheses are proven or disproven about whether a solution (whether a product, process, etc.) creates value for the intended beneficiaries. Participants have to go out into the world and learn by doing. I-Catalyst methods engage customers/stakeholders in a process that will identify what they most value and need, and source solutions that will have high levels of efficacy and user acceptability.

The majority of data will be obtained through on-site, unstructured interviews with individuals who represent the customers or stakeholders CDC teams are attempting to serve or benefit. CDC may also collect information through telephone interviews, questionnaires, or web-based surveys. With each CDC program project, teams will interview their customers/stakeholders with a burden per response ranging from 20–60 minutes (an average of 30 minutes). Each team will interview approximately 25 respondents. With 10–20 teams participating annually and CDC program consultations, approximately 500 respondents will be interviewed. Data to be collected includes information regarding needs, values, and barriers, and facilitators to potential solutions.

CDC expects that teams participating in the I-Catalyst process and OTI consultations will be empowered to implement innovative strategies and solutions that create value for a set of beneficiaries. The ultimate goal is to give CDC staff skills to successfully transfer knowledge into value-based solutions that benefit society and broaden the agency's impact.

In this Revision request, CDC seeks approval for minor changes to the I-Catalyst generic clearance. The number of burden hours will decrease based on participation in the I-Catalyst training program during the period 2017–2019. However, through related technical assistance provided by OTI to CDC/ATSDR programs, CDC has identified additional opportunities for information collection compatible with I-Catalyst goals and methods. During the next three-year period CDC anticipates utilization of the I-Catalyst generic clearance by previous participants in the I-Catalyst training program, as well as other CDC programs implementing customer discovery projects. The title of the clearance is being updated to reflect its use by additional CDC/ATSDR project teams approved by OTI. The I-Catalyst clearance will continue to be used for information collections necessary to explore the needs and preferences of specific stakeholder groups, and to facilitate and improve the acceptance and usability of CDC products, programs, and technologies. All projects submitted to OMB for approval under the I-Catalyst generic

clearance will be consistent with CDC/OTI goals for promoting scientific innovation, customer engagement, and entrepreneurship in public health.

OMB approval is requested for three years. Individual projects must be approved by CDC's OTI before they are submitted to OMB for final review and approval. CDC estimates the estimated annual burden hours to be 250. Participation is voluntary, and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
External Partners, Stakeholders, or Customers.	Interview Guides, Questionnaires, and Surveys.	500	1	30/60	250
Total					250

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–23366 Filed 10–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–1128]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''State Unintentional Drug Overdose Reporting System (SUDORS)'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on April 2, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

State Unintentional Drug Overdose Reporting System (SUDORS) (OMB Control No. 0920–1128, Exp. 10/31/2020)—Revision—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

There has been a rapid increase in opioid overdose deaths since 2013. In the United States, more people are now dying of drug overdose than automobile crashes, although opioids—both opioid pain relievers (OPRs) and illicit forms such as heroin—are also a major factor in overdose-related automobile crashes. On October 26, 2017, the U.S. Department of Health and Human Services (HHS) declared the opioid overdose epidemic to be a national public health emergency.

CDC established the State Unintentional Drug Overdose Reporting System (SUDORS) in order to detect new trends in fatal unintentional drug overdoses, support targeting of drug overdose prevention efforts, and assess the progress of the HHS initiative to reduce opioid misuse and overdoses. Respondents are state- or jurisdiction-level health departments. The SUDORS surveillance system generates detailed, timely public health information on unintentional, fatal opioid-related drug overdoses and has been used to inform prevention and response efforts at the national, state, and local levels. SUDORS consolidates and supplements information available to health departments, including vital statistics and records created by medical examiners and coroners (ME/C). SUDORS is built on a web-based software platform and a collaborative surveillance and data integration model developed by CDC and health departments to improve understanding of homicide, suicide, undetermined deaths, and unintentional firearm deaths (National Violent Death Reporting System (NVDRS), OMB No. 0920–0607, exp. 11/30/2020).

Through SUDORS, CDC currently collects information that is not provided on death certificates, such as whether the drug(s) causing the overdoses were injected or taken orally; a toxicology report on the decedent, if available; and risk factors for fatal drug overdoses including previous drug overdoses, decedent's mental health, and whether the decedent recently exited a treatment program. Without this information, efforts to prevent drug overdose deaths are often based on limited information available on the death certificate and anecdotal evidence.

During the next three years, CDC will update the web-based SUDORS interface to improve system performance, functionality, and accessibility. CDC and health

departments will also expand the SUDORS case definition beyond the current focus on opioid-related overdose deaths to include all individuals who died of an unintentional or undetermined intent drug-related overdose. The expanded focus will allow CDC and health departments to begin characterizing overdose deaths attributable to emerging illicit drug threats (*e.g.,* non-opioid synthetic drugs), deaths attributable to opioid co-use with other classes of drugs (*e.g.,* gabapentin or benzodiazapine), and the extent to which certain types of prescription drugs (both opioid and non-opioid) are involved in fatal overdoses.

Participating states and jurisdictions will continue to report SUDORS information to CDC through a module in the NVDRS web-based platform. State- and jurisdiction-level public health departments will be funded to abstract standardized data elements from ME/C reports as well as death certificates. Beginning in 2020, cooperative agreement goals include reducing the time lag for reporting from eight months to no more than six months. Information can be entered into the SUDORS system at any time, but reports on overdose deaths that occur between January 1 and June 30 will be entered into the SUDORS by December of the same calendar year. Data entry for overdose deaths that occur between July 1 and December 31 will be complete by June of the next calendar year. The accelerated reporting schedule is needed to support timely identification of the causes of overdose deaths, and effective public health intervention.

This Revision request does not entail a change in the estimated burden per response, which is based on the time needed for a health department to retrieve and refile vital statistics records, ME/C records, etc. The estimated burden per response does not include the time needed to abstract SUDORS data variables from those sources, since this activity is funded by the SUDORS cooperative agreement. Total estimated annualized burden will increase due to the inclusion of additional types of overdose-related deaths. Also, increased Congressional appropriation in 2019 to expand SUDORS nationwide as a component of CDC's Overdose Data to Action (OD2A) Notice of Funding Opportunity (NOFO) (CDC–RFA–CE19–1904, posted February 1, 2019) requires expanding the number of participating jurisdictions from 50 to 52. OMB approval is requested for three years. The total estimated annualized burden hours are 32,838.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Total number of responses per respondent	Average burden per response (in hours)
Public Agencies	Retrieving and refiling records	52	1,263	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2019–23367 Filed 10–24–19; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis Meeting (ACET)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting of the Advisory Council for the Elimination of Tuberculosis Meeting (ACET). This meeting is open to the public, limited to 80 room seats and 100 ports for audio phone lines. Time will be available for public comment. The public is welcome to submit written comments in advance of the meeting. Comments should be submitted in writing by email to the contact person listed below. The deadline for receipt is Monday, December 9, 2019. Persons who desire to make an oral statement, may request it at the time of the public comment period on December 11, 2019 at 11:40 a.m., EST.

DATES: The meeting will be held on December 10, 2019, 8:30 a.m. to 4:30 p.m., EST and December 11, 2018, 8:30 a.m. to 12:00 p.m., EST.

ADDRESSES: CDC, 8 Corporate Boulevard, Building 8, Conference Rooms 1–A/B/C, Atlanta, Georgia 30329–4027 and Web conference: 1–877–927–1433 and participant passcode: 12016435 and *https://adobeconnect.cdc.gov/r5p8l2tytpq/.*

FOR FURTHER INFORMATION CONTACT: Margie Scott-Cseh, Committee Management Specialist, CDC, 1600 Clifton Road NE, Mailstop: E–07, Atlanta, Georgia 30329–4027, telephone (404) 639–8317; *zkr7@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: This Council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters To Be Considered: The agenda will include discussions on (1) Use of Project ECHO in supporting tuberculosis (TB) activities; (2) Update on CDC Centers of Excellence for TB Training, Education and Medical Consultation; (3) Update on Latent Tuberculosis Infection (LTBI) communications campaign; (4) TB Host Directed Therapy; and (5) Updates from ACET workgroups. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–23237 Filed 10–24–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #0970–0085]

Submission for OMB Review; Provision of Services in Intergovernmental IV–D; Federally Approved Forms

AGENCY: Office of Child Support Enforcement; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: This is a revision to an existing data collection which expires December 31, 2019. This data collection consists of 13 intergovernmental forms used by States and other entities to process intergovernmental child support cases. This request is for minor revisions to the approved forms.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Public Law 104–193, the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, amended 42 U.S.C. 666 to require State Child Support Enforcement (CSE) agencies to enact the Uniform Interstate Family Support Act (UIFSA) into State law by January 1, 1998. Section 311(b) of UIFSA requires the States to use forms mandated by Federal law. 45 CFR 303.7(a)(4) also requires child support programs to use federally-approved forms in intergovernmental IV–D cases unless a country has provided alternative forms.

Proposed changes to the forms include updates for clarification and consistency to the instructions on all of the forms. Additional changes include:

- On the Child Support Enforcement Transmittal #3—Request for Assistance/Discovery, the addition of a new case processing action to facilitate payment processing for a direct Income Withholding Order, and the revision of the payment forwarding action.
- On the Declaration in Support of Establishing Parentage, the revision of the declaration signature section to make it consistent with the General Testimony and more flexible for cases involved children in foster care.

Respondents: State agencies administering a child support program under title IV–D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Transmittal #1—Initial Request	54	18,246	0.17	167,498
Transmittal #1—Initial Request Acknowledgement *	54	18,246	0.05	49,264
Transmittal #2—Subsequent Action	54	13,685	0.08	59,119
Transmittal #3—Request for Assistance/Discovery	54	2,737	0.08	11,824
Uniform Support Petition	54	7,298	0.05	19,705
General Testimony	54	7,298	0.33	130,050
Declaration in Support of Establishing Parentage	54	2,737	0.15	22,170
Child Support Locate Request	54	182	0.05	491
Notice of Determination of Controlling Order	54	2	0.25	27
Letter of Transmittal Requesting Registration	54	10,948	0.08	47,295
Personal Information Form For UIFSA § 311 *	54	7,298	0.05	19,705
Child Support Agency Confidential Information Form *	54	21,895	0.05	59,117
Request for Change of Support Payment Location Pursuant to UIFSA 319(b) *	54	91	0.05	246

Estimated Total Annual Burden Hours: 586,511.

Authority: 45 CFR 303.7.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–23300 Filed 10–24–19; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4611]

Compliance Policy Guide Sec. 400.400 Conditions Under Which Homeopathic Drugs May Be Marketed; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of Compliance Policy Guide Sec. 400.400 (CPG 400.400) entitled ''Conditions Under Which Homeopathic Drugs May be Marketed,'' which was issued in 1988.

DATES: The withdrawal is applicable October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Elaine Lippmann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6238, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION: FDA is withdrawing CPG 400.400, entitled ''Conditions Under Which Homeopathic Drugs May be Marketed,'' which was issued in 1988. CPG 400.400 described an enforcement policy regarding homeopathic drug products.

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(a)), before any ''new drug'' is marketed, it must be the subject of an approved application filed pursuant to section 505(b) or section 505(j) of the FD&C Act. The requirements in section 505 of the FD&C Act apply to biological products regulated under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262); however, as stated in section 351(j) of the PHS Act, a biological product with an approved license under section 351(a) of the PHS Act is not required to have an approved application under section 505 of the FD&C Act. Accordingly, absent a determination that a homeopathic drug product is not a ''new drug'' under section 201(p) of the FD&C Act (21 U.S.C. 321(p)), all homeopathic drug products are subject to the premarket approval requirements in section 505 of the FD&C Act or section 351 of the PHS Act. There are currently no homeopathic drug products approved by FDA.

Since the issuance of CPG 400.400, the Agency has encountered multiple situations in which homeopathic drug products posed a significant risk to patients. There is a broad misconception that all homeopathic products are highly diluted and generally composed of ''natural'' ingredients, and that they are therefore incapable of causing harm. However, as with all drugs, the safety of homeopathic drugs depends upon many factors, such as the product's intended use, dosage form, frequency of use, manufacturing quality, intended patient population, and the quantity and combination of ingredients. CPG 400.400 does not directly address all these important considerations.

For example, FDA has encountered situations in which homeopathic products either caused or could have caused significant harm, even though the products, as labeled, appeared to meet the conditions described in CPG 400.400. In 2016, FDA's search of the FDA Adverse Event Reporting System database identified 99 cases of adverse events consistent with belladonna toxicity, including reports of infant deaths and seizures, possibly related to teething products. Multiple homeopathic drug products were identified as associated with this safety concern. Further investigation revealed that the poisonous belladonna alkaloids in some of the products far exceeded the labeled amounts, raising a serious safety concern. As another example, by 2009, FDA had received more than 130 reports of anosmia (loss of the sense of smell) associated with the use of Zicam homeopathic intranasal zinc products. FDA determined that if the products were used as labeled, a user would receive significant daily intranasal exposure to zinc, raising a serious safety concern. These are only two examples among many. FDA has also, for example, documented many serious violations of current good manufacturing practice (CGMP) requirements by manufacturers of homeopathic drug products, raising significant concerns about the safety of the products made with inadequate process controls.

The homeopathic drug industry has grown significantly since FDA issued CPG 400.400 in 1988. According to the National Health Interview Survey, conducted by the Centers for Disease Control and Prevention's National Center for Health Statistics, between 2007 and 2012 the use of homeopathic products increased by approximately 15 percent in U.S. adults. This growth, and the increased population exposure that it apparently represents, has contributed to FDA's enhanced focus on the safety of homeopathic drugs in recent years and the evaluation of the CPG, which was issued over three decades ago.

In light of the growth of the industry and passage of time since the issuance of CPG 400.400, FDA announced on March 27, 2015, that it was evaluating its regulatory framework for homeopathic drug products. In April 2015, FDA held a public hearing to obtain information and comments from stakeholders about the current use of homeopathic drug products, as well as the Agency's regulatory framework for such products (Docket No. FDA–2015–N–0540; available at *https://www.regulations.gov/docket?D=FDA-2015-N-0540*). FDA sought broad public input on its enforcement policies related to homeopathic drug products to better promote and protect the public health. On December 18, 2017, FDA issued a draft guidance entitled ''Drug Products Labeled as Homeopathic; Guidance for FDA Staff and Industry.'' The draft guidance detailed a risk-based enforcement policy, prioritizing enforcement and regulatory actions for certain categories of homeopathic products that potentially pose higher risk to public health.

In response to comments received, we have revised the draft guidance and are announcing the reissue of it elsewhere in this issue of the **Federal Register** to enable the public to review and comment before it is finalized. In particular, we have added a definition of ''homeopathic drug product'' for purposes of the guidance, added an additional explanation of some of the safety issues that contributed to the development of the draft guidance, and clarified the intent to use risk-based factors to prioritize enforcement and regulatory actions involving homeopathic products that are marketed without required FDA approval. In addition, the revised draft guidance removes the statement that the Agency will withdraw the CPG simultaneous with the issuance of the final guidance.

As a result of the Agency's ongoing evaluation of its regulatory framework, including consideration of the public input received on this issue and the recent growth of safety concerns associated with homeopathic drug products, FDA believes that it is appropriate to withdraw CPG 400.400 at this time, rather than waiting for the issuance of the final guidance. Because CPG 400.400 is inconsistent with the Agency's risk-based approach to enforcement generally, it does not accurately reflect the Agency's current thinking. When the draft guidance is finalized, it will specify the categories of products that the Agency intends to prioritize for enforcement. In the interim, before the draft guidance is finalized, FDA intends to apply its general approach to prioritizing regulatory and enforcement action, which involves risk-based prioritization in light of all the facts of a given circumstance. Risk-based enforcement best reflects FDA's public health priorities.

We note that withdrawing the CPG does not represent a change in the legal obligations that apply to homeopathic drugs under the statutes FDA administers. The definition of a ''drug'' under section 201(g)(1)(A) through (C) of the FD&C Act includes: (1) Articles recognized in the official United States Pharmacopoeia or the official Homoeopathic Pharmacopoeia of the United States; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals. As such, homeopathic drugs are subject to the same regulatory requirements as other drugs; nothing in the FD&C Act exempts homeopathic drug products from any of the requirements in the FD&C Act, including those related to approval, adulteration, and misbranding.

Generally, a drug, including a homeopathic drug, is considered a ''new drug'' if it is not generally recognized as safe and effective by qualified experts for use under the conditions prescribed, recommended, or suggested in the labeling (section 201(p) of the FD&C Act). CPG 400.400 did not, and legally could not, provide a path for legal marketing of unapproved new drugs, including those that are homeopathic. Rather, the CPG merely described an enforcement policy regarding homeopathic drug products. The Agency does not have authority to exempt a product or class of products that are new drugs under the FD&C Act from the new drug approval requirements of the FD&C Act. (See *Cutler* v. *Kennedy,* 475 F. Supp. 838, 856 (D.D.C. 1979); *Hoffman-LaRoche* v. *Weinberger,* 425 F. Supp. 890, 892–894 (D.D.C. 1975). See also *Util. Air Regulatory Grp.* v. *EPA,* 573 U.S. 302, 327 (2014) (''An agency confronting resource constraints may change its own conduct, but it cannot change the law.'')).

The Agency's interest in its general risk-based enforcement approach also justifies withdrawing an outdated policy that does not reflect that approach. Additionally, withdrawal of the CPG is appropriate given the recent growth of safety concerns associated with homeopathic drug products—including concerns regarding products associated with serious adverse events and otherwise presenting significant safety risks and serious violations of CGMP requirements—and the increasing number of consumer exposures due to the continued expansion of the homeopathic industry since issuance of the CPG.

Dated: October 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23334 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6580]

Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry

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 revised draft guidance for FDA staff and industry entitled ''Drug Products Labeled as Homeopathic.'' The revised draft guidance, like the original version, describes how FDA intends to prioritize enforcement and regulatory action with regard to drug products, including biological products, labeled as homeopathic and marketed in the United States without the required FDA approval that potentially pose higher risk to public health. In response to comments received, we have revised the draft guidance and are reissuing it in draft form to enable the public to review and comment before it is finalized.

DATES: Submit either electronic or written comments on the draft guidance by January 23, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2017–D–6580 for ''Drug Products Labeled as Homeopathic.'' 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building,

4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elaine Lippmann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6238, Silver Spring, MD 20993, 301–796–3600; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** on December 20, 2017 (82 FR 60403), FDA announced the availability of a draft guidance for FDA staff and industry entitled ''Drug Products Labeled as Homeopathic.'' This draft guidance was intended to describe how FDA intends to prioritize enforcement and regulatory action with regard to drug products, including biological products, labeled as homeopathic and marketed in the United States without the required FDA approval that potentially pose higher risk to public health.

In response to comments received, we have revised the draft guidance and are reissuing it to enable the public to review and comment before it is finalized. In particular, we have added a definition of ''homeopathic drug product'' for purposes of the guidance, added additional explanation of some of the safety issues that contributed to the development of the draft guidance, and clarified the intent to use risk-based factors to prioritize enforcement and regulatory actions involving homeopathic products that are marketed without required FDA approval. In addition, the revised draft guidance removes the statement that the Agency will withdraw the compliance policy guide (CPG) simultaneous with the issuance of the final guidance. Elsewhere in this **Federal Register**, FDA is announcing the withdrawal of CPG 400.400.

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 ''Drug Products Labeled as Homeopathic.'' 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.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23335 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2683]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 25, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0847. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Data To Support Social and Behavioral Research as Used by the Food and Drug Administration

OMB Control Number 0910–0847—Extension

Understanding patients, consumers, and healthcare professionals' perceptions and behaviors plays an important role in improving FDA's regulatory decisionmaking processes and communications impacting various stakeholders. The methods used to achieve these goals include individual in-depth interviews, general public focus group interviews, intercept interviews, self-administered surveys, gatekeeper surveys, and focus group interviews. The methods used serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative and quantitative research tool, and have two major purposes:

1. To obtain information that is useful for developing variables and measures for formulating the basic objectives of social and behavioral research and

2. To assess the potential effectiveness of FDA communications, behavioral interventions and other materials in reaching and successfully communicating and addressing behavioral change with their intended audiences.

FDA will use these methods to test and refine its ideas and to help develop communication and behavioral strategies research, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

FDA's Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Office of the Commissioner, and any other Centers or Offices will use this mechanism to test communications and social and behavioral methods about regulated drug products on a variety of subjects related to consumer, patient, or

healthcare professional perceptions, beliefs, attitudes, behaviors, and use of drug and biological products and related materials including, but not limited to, social and behavioral research, decision-making processes, and communication and behavioral change strategies.

Annually, FDA projects about 45 social and behavioral studies using the variety of test methods listed in this document. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the **Federal Register** of June 19, 2019 (84 FR 28557), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys	5,040	14.6	73,584	0.25 (15 minutes)	18,396

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 9,198 hours and a corresponding increase of 36,792 responses due to an increase in grant funding for universities and others to perform research for FDA.

Dated: October 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23268 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0514]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Procedures for Clinical Laboratory Improvement Amendments Categorization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 25, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0607. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization—42 CFR 493.17

OMB Control Number 0910–0607—Extension

FDA's guidance entitled ''*Administrative Procedures for CLIA Categorization*''[1] describes procedures FDA uses to assign the complexity category to a device, which affects what type of Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate the laboratory obtains. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In some cases, however, a manufacturer may request CLIA categorization even if FDA is not simultaneously reviewing a 510(k) or premarket approval application (PMA). One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (*e.g.,* name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

In the **Federal Register** of June 26, 2019 (84 FR 30127), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

[1] Available at *https://www.fda.gov/media/71065/download.*

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Request for CLIA categorization	80	5	400	1	400	$2,000

[1] There are no capital costs associated with this collection of information.

Based on recent receipt data for requests for CLIA categorization separate from a product application, the number of respondents is approximately 80. On average, each respondent requests such categorizations five times per year.

The cost, not including personnel, is estimated at $5 per submission (5 × 400), totaling $2,000. This includes the cost of copying and mailing copies of package inserts and a cover letter. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (*e.g.,* paper). Upon review of this information collection, we have adjusted the estimated cost per submission (previously $52). Because the submissions are typically only a few pages per package insert and copying or printing and postage for a few pages is not expected to be more than $5, we believe this is a more appropriate cost burden estimate.

Our estimated burden for the information collection reflects an overall decrease of 500 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years. Also, upon review of this information collection, we believe the previous estimate may have included requests for categorization associated with a premarket submission, the burden estimate of which is included under the OMB approval for the applicable premarket submission. We have therefore revised the number of respondents/responses to include only those that are separate from a product application, consistent with the scope of this information collection.

Dated: October 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23274 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0190]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 25, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0671. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Requirements Under the Comprehensive Smokeless Tobacco Health Education Act of 1986, as Amended by the Family Smoking Prevention and Tobacco Control Act

OMB Control Number 0910–0671—Extension

The Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act and providing FDA with the authority to regulate tobacco products (Pub. L. 111–31; 123 Stat. 1776). Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (the Smokeless Tobacco Act) (15 U.S.C. 4402), as amended by section 204 of the Tobacco Control Act, requires, among other things, that all smokeless tobacco product packages and advertisements bear one of four required warning statements. Section 3(b)(3)(A) of the Smokeless Tobacco Act requires that the warnings be displayed on packaging and advertising for each brand of smokeless tobacco ''in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer'' to, and approved by, FDA.

This information collection-the submission to FDA of warning plans for smokeless tobacco products is statutorily mandated. The warning plans will be reviewed by FDA, as required by the Smokeless Tobacco Act, to determine whether the companies' plans for the equal distribution and display of warning statements on packaging and the quarterly rotation of warning statements in advertising for each brand of smokeless tobacco products comply with section 3 of the Smokeless Tobacco Act, as amended. Additionally, FDA considers a submission to be a supplement if the submitter is seeking approval of a change to an FDA-approved warning plan.

Based on FDA's experience over the past several years, FDA believes the estimate of 60 hours to complete an initial rotational plan continues to be accurate. If a supplement to an approved plan is submitted, FDA

estimates it will take half the time per response (30 hours).

In the **Federal Register** of June 13, 2019 (84 FR 27638), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Numbers of respondents	Numbers of responses per respondent	Total annual responses	Average burden per response	Total hours	Total capital costs
Submission of Initial rotational plans for health warning statements	4	1	4	60	240	$48
Supplement to approved plan	10	1	10	30	300	120
Total					540	168

[1] There are no operating and maintenance costs associated with this collection of information.

FDA estimates a total of 4 respondents will submit a new original warning plan and take 60 hours to complete a rotational warning plan for a total of 240 burden hours. In addition, 10 respondents will submit a supplement to an approved warning plan at 30 hours per response for a total of 300 hours. The total burden for this collection is estimated to be 540 hours.

Capital costs are based on 14 respondents mailing in their submission at a postage rate of $12 for a 5-pound parcel (business parcel post mail delivered from the furthest delivery zone). Therefore, FDA estimates that the total postage cost for mailing the rotational warning plans to FDA to be $168.

We have adjusted our burden estimate, which has resulted in a decrease of 5,460 hours and 86 respondents to the currently approved burden. We received a total number of 44 original smokeless warning plans, and a total of 17 supplements. After receiving the initial influx of original warnings plans, FDA does not expect to receive as many original warning plans annually. We expect that a few supplements will continue to be received as new products are marketed or as warning plans are revised. We anticipate a total number of 10 supplements submitted annually and 4 original smokeless warning plans.

Dated: October 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23250 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2686]

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing its intent to exempt a list of class II devices from premarket notification requirements, subject to certain limitations. The Agency has determined that, based on established factors, these devices no longer require premarket notification to provide reasonable assurance of safety and effectiveness. FDA is publishing this notice to obtain comments regarding the proposed exemptions, in accordance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the notice by December 24, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 24, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 24, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential 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–2019–N–2686 for ''Medical Devices; Exemptions from Premarket Notification: Class II Devices; 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.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1524, Silver Spring, MD 20993, 301–796–6424, *jismi.johnson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a new device to submit and obtain clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(1)(A) of the FD&C Act requires FDA to publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. FDA is required to publish this notice within 90 days of the date of enactment of the Cures Act and at least once every 5 years thereafter, as FDA determines appropriate. Additionally, FDA must provide at least a 60-day comment period for any such notice required to be published under section 510(m)(1)(A) of the FD&C Act. FDA published this notice in the **Federal Register** of March 14, 2017 (82 FR 13609). Under section 510(m)(1)(B) of the FD&C Act, FDA must publish in the **Federal Register**, within 210 days of enactment of the Cures Act, a list representing its final determination regarding the exemption of the devices that were contained in the list published under section 510(m)(1)(A). FDA published that list in the **Federal Register** of July 11, 2017 (82 FR 31976).

As amended, section 510(m)(2) of the FD&C Act provides that, 1 day after the date of publication of the final list under section 510(m)(1), FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act upon its own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. To do so, FDA must publish in the **Federal Register** a notice of its intent to exempt the device, or of the petition, and provide a 60-day period for public comment. Within 120 days after the issuance of this notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under section 510(m)(2) of the FD&C Act within 180 days of receiving it, the petition shall be deemed granted. FDA is proposing to exempt a list of class II devices from premarket notification requirements, subject to certain limitations, upon its own initiative.

II. Factors FDA May Consider for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (''Class II 510(k) Exemption Guidance'') (Ref. 1). Accordingly, FDA generally considers the following factors to determine whether premarket notification is necessary for class II devices: (1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would still be subject to the limitations on exemptions.

III. Limitations on Exemptions

FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of the class II devices listed in table 1. This determination is based, in part, on the Agency's knowledge of the device, including past experience and relevant reports or studies on device performance (as appropriate), the applicability of general and special controls, and the Agency's ability to limit an exemption.

A. General Limitations of Exemptions

FDA's proposal to grant an exemption from premarket notification for class II devices listed in table 1 applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type. FDA proposes that a manufacturer of a listed device would

still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into commercial distribution when the device meets any of the conditions described in 21 CFR 884.9 to 21 CFR 890.9.

B. Partial Limitations of Exemptions

In addition to the general limitations, FDA may also partially limit an exemption from premarket notification requirements to specific devices within a listed device type when initial Agency assessment determines that the factors laid out in the Class II 510(k) Exemption Guidance (Ref. 1) do not weigh in favor of exemption for all devices in a particular group. In such situations where a partial exemption limitation has been identified, FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for these devices. In table 1, for example, FDA is listing the proposed exemption of the optical position/movement recording system but limits the exemption to such devices that are for prescription (Rx) use only. FDA believes that FDA review (*e.g.,* premarket notification) of an optical position/movement recording system for over-the-counter (OTC) use is necessary to ensure that the exercises and activities led by the system are appropriate for a user's rehabilitation and to assess the measurement accuracy of the system. Additionally, a therapeutic massager to internally massage trigger points in the pelvic floor musculature would exceed the exemption limitation and would require 510(k) review if it is indicated for OTC use, lacks a quantitative feedback mechanism, or lacks a disposable covering.

IV. List of Class II Devices

FDA is identifying the following list of class II devices that, if finalized, would no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions found in §§ 884.9 to 890.9:

TABLE 1—CLASS II DEVICES

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
884.6120	Accessory, Assisted Reproduction	MQG	Exemption is limited to assisted reproduction laminar flow workstations.
884.6180	Media, Reproductive	MQL	Exemption is limited to phosphate-buffered saline used for washing, and short-term handling and manipulation of gametes and embryos; culture oil used as an overlay for culture media containing gametes and embryos; and water for assisted reproduction applications.
888.4505	Instruments Designed for Press-Fit Osteochondral implants.	QBO	
890.5360	System, Optical Position/Movement Recording (Interactive Rehabilitation Exercise Devices).	LXJ	Exemption is limited to prescription (Rx) use only.
890.5670	Massager, Therapeutic, to Internally Massage Trigger Points in the Pelvic Floor Musculature.	OSD	Exemption is limited to prescription (Rx) use only devices which incorporate a quantitative feedback mechanism and a disposable covering.

FDA will assign new product codes to the device types that will be exempt subject to the partial limitations in order to ensure that these devices can be separated from devices that do not fall within the partial exemption limitation under the existing product code (*i.e.,* exempt and non-exempt devices within a device type will have distinct product codes).

FDA is also revising the name of product code LXJ to further clarify the device type that this product code is intended to represent. The device type was previously ''System, Optical Position/Movement Recording.'' This product code also includes types of rehabilitation devices other than optical position/movement recording systems; therefore, to more accurately reflect the devices which fall within this device type (product code LXJ), the device type has been renamed ''Interactive Rehabilitation Exercise Devices.''

V. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* 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.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/media/72685/download.*

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23308 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of vouchers as well as the approval of products redeeming a

voucher. FDA has determined that an efficacy supplement for DESCOVY (emtricitabine and tenofovir alafenamide) approved October 3, 2019, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9858, email: *althea.cuff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that an efficacy supplement for DESCOVY (emtricitabine and tenofovir alafenamide) approved October 3, 2019, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm*. For further information about DESCOVY (emtricitabine and tenofovir alafenamide) efficacy supplement approved October 3, 2019, go to the ''*Drugs@FDA*'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/*.

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23252 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2013–N–0719]

Agency Information Collection Activities; Proposed Collection; Comment Request; Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection for the guidance on planning for the effects of high absenteeism to ensure availability of medically necessary drug products.

DATES: Submit either electronic or written comments on the collection of information by December 24, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 24, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 24, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential 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–2013–N–0719 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://*

www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

OMB Control Number 0910–0675—Extension

This information collection supports recommendations found in Agency guidance. Specifically, we have developed guidance intended to encourage manufacturers of drug and therapeutic biological products, and any raw materials and components used in those products, to develop a written Emergency Plan (Plan) for maintaining an adequate supply of medically necessary drug products (MNPs) during an emergency that results in high employee absenteeism. The guidance document entitled, ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products,'' discusses the elements that should be covered by such a Plan, and is available from our website at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/planning-effects-high-absenteeism-ensure-availability-medically-necessary-drug-products*.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Activate/deactivate Plan as recommended in the guidance	2	1	2	16	32

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Develop initial Plan as recommended in the guidance	70	1	70	250	17,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

As explained in the guidance, we provide recommendations for developing and implementing a written Plan, including: (1) Identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate the Plan and make decisions during the emergency; (2) prioritizing the manufacturer's drug products based on medical necessity; (3) identifying actions that should be taken prior to an anticipated period of high absenteeism; (4) identifying criteria for activating the Plan; (5) performing quality risk assessments to determine which manufacturing activities may be reduced to enable the company to meet a demand for MNPs; (6) returning to normal operations and conducting a post-execution assessment of the execution outcomes; and (7) testing the Plan.

The guidance also encourages manufacturers to include and document procedures in the Plan for notifying the FDA Center for Drug Evaluation and Research (CDER) when the Plan is activated and when returning to normal operations. The guidance recommends that these notifications occur within 1 day of a Plan's activation and within 1 day of a Plan's deactivation. The guidance identifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products' manufacturing will be temporarily delayed, and any anticipated or potential drug shortages. We assume two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be submitted to CDER

annually, and assume each notification requires 16 hours to prepare and submit.

Finally, the guidance recommends developing a Plan for each individual manufacturing facility as well as a broader Plan that addresses multiple sites within the organization. For purposes of this information collection analysis, we consider the Plan for an individual manufacturing facility and the broader Plan to comprise one Plan for each manufacturer. Based on available data on the number of manufacturers that would be covered by the guidance, we previously estimated 70 manufacturers will develop a Plan as recommended by the guidance (*i.e.,* one Plan per manufacturer, to include all manufacturing facilities, sites, and drug products) and that each Plan would take approximately 500 hours to develop. Upon development of the plan, however, we believe fewer hours are necessary to maintain and update it as needed. As FDA issued the guidance in 2011, we now assume that most respondents have developed the recommended plan, and therefore we limit our current burden estimate to updates and maintenance. Accordingly, we have reduced our estimate by half, reasoning that, although it takes fewer hours for updates and maintenance, new respondents may choose to adopt recommendations found in the guidance.

Dated: October 16, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23272 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4310]

Allergan Pharmaceuticals International, LTD; Withdrawal of Approval of a New Drug Application for LO MINASTRIN FE

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of a new drug application (NDA) for LO MINASTRIN FE (ethinyl estradiol tablets, 0.01 milligrams (mg); ethinyl estradiol and norethindrone acetate tablets, 0.01 mg/1mg; and ferrous fumarate tablets, 75 mg), held by Allergan Pharmaceuticals International, LTD, c/o Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940 (Allergan). Allergan notified the Agency in writing that the drug product was no longer marketed and requested that the approval of the application be withdrawn.

DATES: Approval is withdrawn as of November 25, 2019.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: Allergan has informed FDA that LO MINASTRIN FE (ethinyl estradiol tablets, 0.01 mg; ethinyl estradiol and norethindrone acetate tablets, 0.01 mg/1 mg; and ferrous fumarate tablets, 75 mg) is no longer marketed and has requested that FDA withdraw approval of NDA 204654 under the process in § 314.150(c) (21 CFR 314.150(c)). Allergan has also, by its request, waived its opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Therefore, approval of NDA 204654, and all amendments and supplements thereto, is hereby withdrawn as of November 25, 2019. Approval of the entire application is withdrawn, including any strengths and dosage forms inadvertently missing from this notice. Introduction or delivery for introduction into interstate commerce of a product without an approved new drug application violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Any Lo Minastrin Fe that is in inventory on November 25, 2019 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.

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23309 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–N–3163; FDA–2012–D–0429; FDA–2012–D–0049; FDA–2018–N–3031; FDA–2011–D–0125; FDA–2018–N–4428; FDA–2012–N–0560; FDA–2010–N–0414; FDA–2012–N–1203; and FDA–2019–N–0430]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA).

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Physician Interpretation of Information About Prescription Drugs in Scientific Publications Versus Promotional Pieces	0910–0875	9/30/2021
Guidance on Meetings with Industry and Investigators on the Research and Development of Tobacco Products	0910–0731	8/31/2022

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

Title of collection	OMB control No.	Date approval expires
Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act	0910–0732	8/31/2022
Tobacco Products, User Fees, Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Tobacco	0910–0749	8/31/2022
Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007	0910–0775	8/31/2022
Medicated Feed Mill License Application	0910–0337	9/30/2022
Guidance on Informed Consent for In Vitro Diagnostic Studies Using Leftover Human Specimens That Are Not Individually Identifiable	0910–0582	9/30/2022
Manufactured Food Regulatory Program Standards	0910–0601	9/30/2022
Information to Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements	0910–0661	9/30/2022
Generic Clearance for Quick Turnaround Testing of Communication Effectiveness	0910–0876	9/30/2022

Dated: October 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23251 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4560]

Pediatric Stakeholder Meeting; 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's (FDA or the Agency) Office of Pediatric Therapeutics (OPT), the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) are announcing a public meeting seeking input from patient/parent groups, consumer groups, regulated industry, academia, and other interested parties to obtain any recommendations or information relevant to the report to Congress that FDA is required to submit concerning pediatrics, as outlined in section 508 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (see the **SUPPLEMENTARY INFORMATION** section for additional background information).

DATES: The public meeting will be held on November 21, 2019, from 9 a.m. to 3 p.m. Registration to attend the meeting should be received by November 15, 2019. Onsite registration on the day of the meeting will be based on space availability. Submit either electronic or written comments on the public meeting by December 19, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (1503–A), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For information on parking and security procedures, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 19, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as 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–2019–N–4560 for ''Pediatric Stakeholder Meeting.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docker 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 CR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Terrie Crescenzi, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *terrie.crescenzi@fda.hhs.gov* or Elizabeth Sanford, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, *elizabeth.sanford@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub L. 112–144). Section 508 of FDASIA directs the Secretary of HHS to submit a report to Congress on the implementation of the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA). The first report was required to be submitted to Congress by July 9, 2016, and subsequent reports are required every 5 years thereafter. FDASIA also requires FDA to obtain, at least 180 days prior to submission of the report, stakeholder input from patient groups, consumer groups, regulated industry, academia, and any other interested parties to obtain any recommendations or information relevant to the report including suggestions for modifications that would improve pediatric drug research and pediatric labeling of drugs and biological products. In addition, on August 18, 2017, the Food and Drug Administration Reauthorization Act (FDARA) (Pub L. 115–52) was signed into law, which outlined additional requirements to be included in the report.

Some of the issues to be discussed at the meeting will include, but not be limited to:

- Hearing from patients/parents and patient/parent groups, industry, academia and other stakeholders about the public health impact that pediatric legislation may have had on them or their communities;
- Understanding the effects of the requirement of pediatric studies under PREA or the incentives under BPCA on drug/biologic development plans; and
- Understanding if there are any barriers or resource issues preventing undertaking or completing studies under PREA and BPCA.

II. Meeting Attendance and Participation

If you wish to attend this meeting, visit *https://www.eventbrite.com/e/stakeholder-input-on-pediatric-legislation-registration-74306461627.* Please register by November 15, 2019. Those who are unable to attend the meeting in person can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast. Your registration will also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Seating will be limited so early registration is recommended. Registration is free and will be on a first-come, first-served basis. Onsite registration on the day of the meeting will be based on space availability. To view the webcast, visit: *https://collaboration.fda.gov/pediatric legislation/.* If you need special accommodations due to a disability, please contact Elizabeth Sanford (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance. Persons attending the meeting are advised that FDA is not responsible for providing access to electrical outlets.

Persons interested in presenting comments at the meeting will be asked to indicate this in their registration. If you intend to use a PowerPoint presentation, please email the presentation to *opt@fda.hhs.gov* by November 15, 2019. FDA will try to accommodate all participant requests to speak, however the duration of comments may be limited by time constraints.

Comments: Regardless of attendance at the public meeting, you can submit electronic or written comments to the public docket (see **ADDRESSES**) by December 19, 2019. Received comments may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23264 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0283]

Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act; Draft 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 draft guidance for industry entitled ''Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance revises the guidance for industry of the same name issued April 1, 2011. The draft guidance is being revised to describe the multiple factors that FDA considers, before requiring a postmarketing study or clinical trial for the purposes described in the Federal Food, Drug, and Cosmetic Act (FD&C Act), when determining the sufficiency of the reports under the FD&C Act and the active postmarket risk identification and analysis (ARIA) system available under the FD&C Act to meet these purposes. The draft guidance is also being revised to reflect certain provisions enacted under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act as they relate to postmarketing studies and clinical trials.

DATES: Submit either electronic or written comments on the draft guidance by December 24, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2009–D–0283 for ''Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability.'' 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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ayanna Augustus, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6426, Silver Spring, MD 20993–0002, 301–796–3980; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled, ''Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act.''

Section 505(o)(3) of the FD&C Act [1] (21 U.S.C. 355(o)) authorizes FDA to require certain postmarketing studies or clinical trials for prescription drugs to obtain more information about a serious risk that may be associated with a drug. In some cases, FDA may be concerned about a serious risk that is potentially or known to be associated with a drug but may not know enough about the risk to determine if or how to address it, such as by describing the risk in labeling. Section 505(o)(3)(B) of the FD&C Act states that postmarketing studies and clinical trials may be required for any or all of the following purposes: (1) To assess a known serious risk related to the use of the drug; (2) to assess signals of serious risk related to the use of the drug; or (3) to identify an unexpected serious risk when available data indicates the potential for a serious risk.

Prior to requiring a postmarketing study or clinical trial, FDA must find that the reports under section 505(k)(1) of the FD&C Act and the ARIA system [2] made available under section 505(k)(3) of the FD&C Act will not be sufficient to meet the purposes described in section 505(o)(3)(B) of the FD&C Act.[3] Similarly, before requiring a postmarketing clinical trial, FDA must find that a postmarketing study will not be sufficient to meet the purposes

[1] Section 901 of Title IX of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) amended the FD&C Act by adding section 505(o).

[2] Section 505(k)(3) of the FD&C Act mandates that FDA establish an active surveillance system for monitoring drugs, using electronic data from healthcare information holders. The Sentinel System draws on existing healthcare data from multiple sources to actively monitor the safety of medical products. The ARIA system is a subcomponent of the Sentinel System.

[3] Section 505(o)(3)(D)(i) of the FD&C Act.

described in section 505(o)(3)(B) of the FD&C Act.[4]

In April 2011, FDA issued a guidance describing how it would implement section 505(o) of the FD&C Act. At that time, the ARIA system was still in early development. The ARIA system is now officially launched, and FDA must consider the system's sufficiency to meet the purposes of section 505(o)(3)(B) of the FD&C Act to determine if a postmarketing study or clinical trial is necessary. This draft guidance revises the guidance for industry of the same name issued on April 1, 2011 (76 FR 18226). Significant changes from the 2011 version include explaining how FDA considers the reporting under section 505(k)(1) of the FD&C Act and the ARIA system when determining their sufficiency for the purposes under section 505(o)(3)(B) of the FD&C Act. The guidance is also being revised to provide examples of postmarketing requirements under section 505(o)(3) of the FD&C Act to assess a potential reduction in the expected effectiveness of a drug under certain circumstances. FDA's authority to require these types of studies or trials was clarified by a modification to the definition of *adverse drug experience* at section 505–1(b)(1)(E) of the FD&C Act (21 U.S.C. 505–1(b)(1)(E)) enacted under section 3041 of the SUPPORT Act (Pub. L. 115–271).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking on implementation of section 505(o)(3)(B) of the FD&C Act. 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.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

The following collections of information for postmarketing reports and clinical data in 21 CFR 314.50, 314.80, 314.81, 314.98, 314.430, and 314.610(b), subpart I have been approved under OMB control number 0910–0001: (1) Preparing and submitting reports pertaining to safety, postmarketing commitments and preparing and submitting spontaneous and periodic reports, including active postmarket risk identification (using electronic health care data) and any milestones or submissions for which projected dates were specified as part of the postmarketing commitment; (2) submitting a proposed timetable of the postmarketing commitments; (3) preparing registries and submitting them when appropriate; (4) designing meta-analyses to evaluate statistical analyses of data; (5) preparing assay procedures; and (6) prepare a plan or approach for approval an NDA when human efficacy studies are not ethical or feasible.

The following collections of information for postmarketing studies and clinical trials (including various patient populations) in 21 CFR 312.23 have been approved under OMB control number 0910–0014: (1) Conducting in vitro laboratory tests and studies to compare pregnancy incidence an pregnancy outcomes and/or child outcomes for patients exposed to a drug; (2) submitting an introductory statement and general investigational plan, including a drug's pharmacological class; and (3) submitting protocols for drug safety and pharmacology and toxicology information.

The collections of information in 21 CFR 310.305, 314.80, and 314.98 for submitting adverse event information to the FDA Adverse Event Reporting System have been approved under OMB control numbers 0910–0230 and 0910–0291; the collections of information in 21 CFR 312.47 and 312.82 for submitting a meeting request to appeal the conduct of a postmarketing study or clinical trial have been approved under OMB control number 0910–0430 (and guidance for industry and review staff entitled ''Formal Dispute Resolutions: Appeals Above the Division Level'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm343101.pdf*).

The following collection of information in § 314.510 has been approved under OMB control number 0910–0765: Requests for serious or life-threatening diseases or conditions that may be granted accelerated approval if FDA determines the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality or other clinical benefit.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: October 21, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23312 Filed 10–24–19; 8:45 am]

BILLING CODE 4164–01–P

[4] Section 505(o)(3)(D)(ii) of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Evidence-based Screening in Diverse Adult Populations.

Date: November 15, 2019.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Karen Nieves Lugo, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health Bethesda, MD 20892, 301–594–9088, *karen.nieveslugo@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cancer Diagnostics and Treatments (CDT).

Date: November 18–19, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Zhang-Zhi Hu, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6186,

MSC 7804, Bethesda, MD 20892, (301) 437–8135, *huzhuang@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Infectious Diseases and Microbiology Research Enhancement Review.

Date: November 18, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Liangbiao Zheng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3202, MSC 7808, Bethesda, MD 20892, 301–996–5819, *zhengli@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Drug Discovery and Development.

Date: November 18, 2019.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301–435–1180, *ruvinser@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AI19–024/025: US South Africa Program for Collaborative Biomedical Research.

Date: November 18, 2019.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marci Scidmore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301–435–1149, *marci.scidmore@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Electronic Nicotine Delivery Systems (ENDS): Population, Clinical and Applied Prevention Research.

Date: November 18, 2019.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Miriam Mintzer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, Bethesda, MD 20892, 301–523–0646, *mintzermz@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Medical Imaging Investigations.

Date: November 19, 2019.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Biology.

Date: November 19, 2019.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Charles Morrow, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301–451–4467, *morrowcs@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Retinopathies, Cornea Regeneration and Strabismus.

Date: November 19, 2019.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alessandra C. Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205, MSC7846, Bethesda, MD 20892, (301) 435–1021, *rovescaa@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Health Services Organization and Delivery.

Date: November 19, 2019.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jessica Bellinger, Ph.D., Scientific Review Administrator, Center for Scientific of Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, 301–827–4446, *bellingerjd@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23278 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute, November 4, 2019, 9:00 a.m. to 3:45 p.m., National Institutes of Health, Building 45, Natcher Building, Conference Room D, 45 Center Drive, Bethesda, MD 20892, which was published in the **Federal Register** on February 15, 2019, 84 FR 4487.

This meeting notice is amended to add an open session from 9:05 a.m. to 9:35 a.m. to present Remarks from the Acting Director, NCI and to change the meeting end time from 3:45 p.m. to 5:00 p.m. The meeting is partially closed to the public.

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23282 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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 Drug Abuse Special Emphasis Panel; Identification of Genetic and Genomic Variants by Next-Gen Sequencing in Non-human Animal Models (U01).

Date: November 1, 2019.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001

Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4228, MSC 95509529, Bethesda, MD 20892, *ramadanir@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; SEP for NIDA Medications Development.

Date: November 4, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Ivan K. Navarro, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4242, MSC 9550, Bethesda, MD 20892, 301–827–5833, *ivan.navarro@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Cutting-Edge Basic Research Awards (CEBRA) (R21-Clinical Trial Optional).

Date: November 4, 2019.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, 301–435–1426, *mcguireso@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Advancing Exceptional Research on HIV/AIDS and Substance Abuse (R01, Clinical Trial Optional).

Date: November 4, 2019.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, 301–402–6020, *hiromi.ono@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Blockchain Technology to Improve SUD Care.

Date: November 5, 2019.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4235, MSC 9550, Bethesda, MD 20892–9550, 301–827–5819, *gm145a@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIH Pathway to Independence Award (K99/R00) & NIDA Mentored Clinical Scientist Development Program (K12).

Date: November 8, 2019.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, 301–435–1426, *mcguireso@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 21, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23291 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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; Member Conflict SEP.

Date: October 31, 2019.

Time: 2:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ramesh Vemuri, Ph.D., Chief, Scientific Review Branch, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301–402–7700, *rv23r@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23279 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, November 1, 2019 at the Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on October 08, 2019, 84 FR 53743.

The meeting format of the Special Emphasis Panel; U.S.—South Africa Program for Collaborative Biomedical Research—Phase 2 (HIV/AIDS) has been changed to Regular plus Video Conference. The meeting date, time and location remain the same. The meeting is closed to the public.

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23285 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (Parent R13 Clinical Trial Not Allowed).

Date: November 4–6, 2019.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Ellen S. Buczko, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3F30A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9824, Bethesda, MD 20892–9824, (240) 669–5028, *ebuczko1@niaid.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 21, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23281 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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; SWAN.

Date: November 18, 2019.

Time: 11:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Isis S. Mikhail, MD, MPH, DrPH, Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, Tel: 301–402–7704, mikhaili@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23290 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Summer Research Internship Program (National Institute on Drug Abuse)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Albert Avila, Director, National Institute on Drug Abuse, Office of Diversity and Health Disparity, Neuroscience Center, Building 6001, Room 3106, Rockville, Maryland 20852 or call non-toll-free number (301) 496–8804 or Email your request, including your address, to: *aavila@nida.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on March 12, 2019, page 8881 (84 FR 8881) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute on Drug Abuse (NIDA), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection Title: NIDA Summer Research Internship Program, 0925–0738, Expiration 03/31/2019, REINSTATEMENT WITH CHANGE, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of the proposed information is for the selection of

interns for the continuing NIDA Summer Research Internship Program. This request is to allow NIDA to collect information from applicants in order to meet the goals of the program and IC mission. Applicant eligibility for this program was 17 years, but is now open to those 18 and over in the year of application per NIH policy document 2019 High School Summer Internship Program (HS–SIP) Policy. NIDA will request clearance for any additional forms should new programs be introduced in the future. The information ensures that students applying to this program meet basic eligibility requirements; indicates their interest in substance abuse research, future career goals, and, if selected for the program, what research they prefer to conduct. The information also enables decision-making regarding which applicants will be selected for internships. In each case, completing the application is voluntary, but in order to receive due consideration, the prospective applicant must complete all fields required by the program.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 250.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Estimated total annual burden hours
Summer Internship	Individuals-household	250	1	1	250
Total			250		250

Dated: October 16, 2019.

Lanette A. Palmquist,

Project Clearance Liaison, National Institute on Drug Abuse, National Institutes of Health.

[FR Doc. 2019–23283 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Workshop

Notice is hereby given of a workshop convened by the National Center for Advancing Translational Sciences Cures Acceleration Network Review Board.

Purpose

The National Center for Advancing Translational Sciences is hosting the Cures Acceleration Network Review Board (CAN RB) Workshop: The CAN RB advises and provides recommendations to the NCATS Director with respect to significant barriers to successful translation of basic science into clinical application. In support of this mandate, the CAN RB will co-host this public workshop to discuss challenges around finding new uses for drugs that are already on the market but lack commercial and regulatory incentives for research and development.

The Workshop is being co-sponsored by the NCATS Cures Acceleration Network Review Board, NCATS Drug Development Partnership Programs, Food and Drug Administration, and Reagan-Udall Foundation for the FDA.

Name of Committee: National Center for Advancing Translational Sciences Cures Acceleration Network Review Board.

Type of Meeting: Repurposing Off-Patent Drugs: Research & Regulatory Challenges.

Date: December 5–6, 2019.

Time: 7:30 a.m. to 5:00 p.m., Eastern Standard Time (EST).

Agenda: The Workshop will assess challenges around finding new uses for drugs that are already on the market but lack commercial and regulatory incentives for research and development. On December 5, we will map out the challenges to repurposing off-patent drugs. On December 6, we will host interactive work sessions focused on capturing possible solutions.

Place: Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Cost: The meeting is free and open to the public.

Registration: Registration is required. Using the link below, attendees can register by December 2, 2019, 5:00 p.m. EST. Early registration is recommended due to limited seating. *https://reaganudall.salsalabs.org/repurposingoffpatentdrugsworkshop/index.html.*

Access: Twinbrook Metro Station (Red Line).

Contact Person: Bobbie Ann Mount, Ph.D., Program Officer, Drug Development Partnership Programs, Office of the Director, National Center for Advancing Translational Sciences, National Institutes of Health. *Telephone:* 301.435.0824, Email: *NewTherapeuticUses@mail.nih.gov.*

Disability Accommodations: Individuals whose full participation in the workshop will require special accommodations (*e.g.,* sign language, or interpreting services, etc.) must submit a request to the Contact Person listed on the notice at least ten (10) business days prior to the meeting. Such requests should include a detailed description of the accommodation needed and a way to contact the requester if more information is needed to fill the request. Special requests should be made as early as possible. Last minute requests may be made but may not be possible to accommodate.

Security: Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Also, as a part of security procedures, attendees should be prepared to present a photo ID at the meeting registration desk during the check-in process. Pre-registration is recommended. Seating will be limited to the room capacity and seats will be on a first come, first serve basis, with expedited check-in for those who are pre-registered.

Meeting schedule subject to change.

For more information, visit: *https://reaganudall.salsalabs.org/repurposingoffpatentdrugsworkshop/index.html.*

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23280 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biological Chemistry, Biophysics and Assay Development.
Date: November 14–15, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: John Harold Laity, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–402–8254, *john.laity@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Endocrinology, Metabolism, Nutrition and Reproductive Sciences.
Date: November 18, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW, Washington, DC 20008.
Contact Person: Yunshang Piao, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 6184, Bethesda, MD 20892, 301–402–8402, *piaoy3@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Electronic Nicotine Delivery Systems (ENDS): Population, Clinical and Applied Prevention Research.
Date: November 18, 2019.
Time: 12:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Marc Boulay, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, 301–300–6541, *boulaymg@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Instrumentation, Environmental and Occupational Safety.
Date: November 19–20, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.
Contact Person: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 6188, MSC 7804, Bethesda, MD 20892, 301–435–1267, *belangerm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cell and Molecular Biology.
Date: November 19–20, 2019.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.
Contact Person: Amy Kathleen Wernimont, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, Bethesda, MD 20892, 301–827–6427, *amy.wernimont@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Orthopedic, Skeletal Muscle and Oral Sciences.
Date: November 19–20, 2019.
Time: 8:30 a.m. to 5:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Radisson Hotel Fossil Creek, 2540 Meacham Boulevard, Fort Worth, TX 76106.
Contact Person: Aftab A. Ansari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, 301–237–9931, *ansaria@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Sleep, Movement, Mood and Olfaction.
Date: November 19, 2019.
Time: 10:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Janita N. Turchi, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda 20892, 301–402–4005, *turchij@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: U.S. Tobacco Control Policies to Reduce Health Disparities.
Date: November 19, 2019.
Time: 1:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).
Contact Person: Kristen Prentice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3112, MSC 7808, Bethesda, MD 20892, 301–496–0726, *prenticekj@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Commercialization Readiness Pilot.
Date: November 19, 2019.
Time: 2:00 p.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.
Contact Person: Amy Kathleen Wernimont, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6198, Bethesda, MD 20892, 301–827–6427, *amy.wernimont@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 21, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23286 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Scientific Counselors for Basic Sciences National Cancer Institute, November 5, 2019, 9:00 a.m. to 4:00 p.m., National Institutes of Health, Building 45, Natcher Building, Conference Room D, 45 Center Drive, Bethesda, MD 20892, which was published in the **Federal Register** on February 15, 2019, 84 FR 4487.

This meeting notice is amended to add an open session from 9:05 a.m. to 9:35 a.m. to present Remarks from the Acting Director, NCI and to change the meeting end time from 4:00 p.m. to 2:45 p.m. The meeting is partially closed to the public.

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23287 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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; Hallmarks of Aging and AD I.

Date: October 29, 2019.

Time: 10:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Nijaguna Prasad, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institute of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301–496–9667, *nijaguna.prasad@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23288 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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; Dementia and AD.

Date: November 12, 2019.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alicja L. Markowska, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–7706, *Markowsa@Nia.Nih.Gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 21, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23289 Filed 10–24–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7011–N–47]

30-Day Notice of Proposed Information Collection: Enterprise Income Verification Systems Debts Owed to Public Housing Agencies and Terminations

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, PIH, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* November 25, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Departmental Paperwork Reduction Act Officer, OCIO, Department of Housing and Urban Development, 451 7th Street SW, Room 4186 Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW, (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–4109, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Mussington.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comments on the information for a period of 60 days was published on May 20, 2019.

A. Overview of Information Collection

Title of Information Collection: EIV System Debts Owed to PHAs and Terminations.

OMB Approval Number: 2577–0266.

Type of Request: Revision of a currently approved collection.

Form Number: Form HUD–52675.

Description of the need for the information and proposed use: In accordance with 24 CFR 5.233, processing entities that administer the Public Housing, Section 8 Housing Choice Voucher, including the Disaster Housing Assistance Program, Section 8 Moderate Rehabilitation Program and, Project-Based Vouchers are required to use HUD's Enterprise Income Verification (EIV) system to verify employment and income information of program participants and to reduce administrative and subsidy payment errors. The EIV system is a system of records owned by HUD, as published in the **Federal Register** on July 20, 2005 at 70 FR 41780 and updated on September 1, 2009 at 71 FR 45235.

The Department seeks to identify families who no longer participate in a HUD rental assistance program due to adverse termination of tenancy and/or assistance and owe a debt to a Public Housing Agency (PHA). In accordance with 24 CFR 982.552 and 960.203, the PHA may deny admission to a housing program if the family is not suitable for tenancy for reasons such as, but not limited to: Unacceptable past performance in meeting financial obligations, history of criminal activity, eviction from Federally assisted housing in the last five years, family has committed fraud, bribery, or any other corrupt or criminal act in connection with any Federal housing program, or if a family currently owes rent or other amounts to the PHA or to another PHA in connection with a Federally assisted housing program under the U.S. Housing Act of 1937.

Within the scope of this collection of information, HUD seeks to collect from all PHAs, the following information:

1. If applicable, amount of debt owed by a former tenant to a PHA;
2. If applicable, indication of executed repayment agreement;
3. If applicable, indication of bankruptcy filing;
4. If applicable, the reason for any adverse termination of the family from a Federally assisted housing program.

This information is collected electronically from PHAs via HUD's EIV system. The information is used by HUD to create a national repository of families that owe a debt to a PHA and/or have been terminated from a federally assisted housing program. This national repository is available within the EIV system for all PHAs to access during the time of application for rental assistance. PHAs are able to access this information to determine a family's suitability for rental assistance, and avoid providing limited Federal housing assistance to families who have previously been unable to comply with HUD program requirements. If this information is not collected, the Department is at risk of paying limited Federal dollars on behalf of families who may not be eligible to receive rental housing assistance. Furthermore, if this information is not collected, the public will perceive that there are no consequences for a family's failure to comply with HUD program requirements.

Respondents: Public Housing Agencies.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Form HUD 52675	3834	12	46,008.00	0.53992	24,840.63	$23.07	$573,073.33

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(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 the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: October 17, 2019.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2019–23395 Filed 10–24–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7111–N–38A]

Notice of Approved Proposed Information Collection: FHA Lender Approval, Annual Renewal, Periodic Updates and Required Reports by FHA-Approved Lenders

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA), HUD is notifying FHA-approved lenders that HUD's information collection entitled, FHA Lender Approval, Annual Renewal, Periodic Updates and Required Reports by FHA-Approved Leaders, has been approved by the Office of Management and Budget. HUD is notifying FHA-approved lenders that the final annual certification will be effective beginning with lenders that have a Fiscal Year End date of December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Volky Garcia, Director, Lender Approval and Recertification Division, Office of Lender Activities and Program Compliance, Office of Single Family Housing, U.S. Department of Housing and Urban Development, 490 L'Enfant Plaza East SW, Room P3214, Washington, DC 20024–8000; email *Volky.A.Garcia@hud.gov,* or telephone 202–402–8229. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: On March 12, 2019 (84 FR 8888), HUD initiated the process to renew approval of information collection 2502–0005 by publishing a 60-day notice in the **Federal Register**. HUD's collection sought a revision to OMB's approval of 2502–0005 that expired on August 31, 2019. Specifically, the proposed revisions aligned the recertification statements with the National Housing Act (12 U.S.C. 1701, et seq) and clarified HUD requirements. Additionally, the revisions combined multiple statements to reflect statute, regulations and Handbook and sought to remove inapplicable language in statements for Government and Investing lenders or mortgagees.

On August 14, 2019 (84 FR 40436), HUD published its 30-day notice requesting OMB approval of this information collection. In addition to its 30-day notice, HUD provided the public the opportunity to review and comment on its FHA Annual Lender Certification through its FHA Office of Single Family Housing ''Drafting Table.'' *https://www.hud.gov/program_offices/housing/sfh/SFH_policy_drafts*. HUD received positive feedback with minor suggestions regarding the proposed changes to FHA's Annual Certification. The commenters recommended that HUD: (1) Immediately implement the proposal (2) capitalize the word Sanction to align with the HUD's Single

Family Housing Handbook 4000.1 and (3) add language at the end of the statements clarifying the redisclosure of previous issues reported to HUD during a Mortgagees certification period. In response to the feedback and recommendations, HUD developed a streamlined FHA Annual Lender Certification which is available at *https://www.hud.gov/program_offices/housing/sfh/lender/approvals_renewals/sfh_recertification*. Today's notice announces that OMB has provided its Notice of Action approving HUD's collection.

FHA approves entities to participate as FHA-approved lenders. Specific information must be obtained and reviewed to determine if an entity meets the criteria to obtain the requested approval. HUD's submission covers information required by FHA from approved lenders to renew and maintain their approval, make periodic updates to their approval, submit required reports to FHA and submit requests to voluntarily terminate their FHA approval.

As approved collections, FHA-approved lenders are now required to use the revised FHA Lender Approval, Annual Renewal, Periodic Updates and Required Reports by FHA-Approved Lenders information collection. As a result, FHA-approved lenders that have a Fiscal Year End date of December 31, 2019 will be required to use HUD's revised collection.

Dated: October 21, 2019.

John L. Garvin,

General Deputy Assistant Secretary, Office of Housing.

[FR Doc. 2019–23241 Filed 10–24–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6185–N–01]

Manufactured Housing Consensus Committee (MHCC): Notice Inviting Nominations of Individuals To Serve on the Committee

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of request for nominations to serve on the Manufactured Housing Consensus Committee.

SUMMARY: The Department of Housing and Urban Development invites the public to nominate individuals for appointment, with the approval of the Secretary, to the Manufactured Housing Consensus Committee (MHCC), a federal advisory committee established by the National Manufactured Housing Construction and Safety Standards Act of 1974, as amended by the Manufactured Housing Improvement Act of 2000. The Department will make appointments from nominations submitted in response to this Notice. Also, individuals that applied last year do not need to re-apply; pursuant to this notice those applications are on file and may be considered for future appointments.

DATES: The Department will accept nominations until November 25, 2019.

ADDRESSES: Nominations must submit through the following website: *http://mhcc.homeinnovation.com/Application.aspx.* The submitted nominations are addressed to Teresa B. Payne, Administrator, Office of Manufactured Housing Programs, Department of Housing and Urban Development, c/o Home Innovation Research Labs; Attention: Kevin Kauffman, 400 Prince Georges Blvd., Upper Marlboro, MD 20774.

FOR FURTHER INFORMATION CONTACT: Teresa B. Payne, Administrator, Office of Manufactured Housing Programs, Department of Housing and Urban Development, 451 7th Street SW, Room 9166, Washington, DC 20410–8000; telephone number 202–708–5365 (this is not a toll-free number). For hearing and speech-impaired persons, this number may be accessed via TTY by calling the Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Background

Section 604 of the Manufactured Housing Improvement Act of 2000 (Pub. L. 106–569) amended the National Manufactured Housing Construction and Safety Standards Act of 1974 (42 U.S.C. 5401–5426) (Act) to require the establishment of the MHCC, a federal advisory committee, to: (1) Provide periodic recommendations to the Secretary to adopt, revise, and interpret the manufactured housing construction and safety standards; and (2) to provide periodic recommendations to the Secretary to adopt, revise, and interpret the procedural and enforcement manufactured housing regulations. The Act authorizes the Secretary to appoint a total of twenty-two members to the MHCC. Twenty-one members have voting rights; the twenty-second member represents the Secretary and is a non-voting position. Service on the MHCC is voluntary. Travel and per diem for meetings is provided in accordance with federal travel policy pursuant to 5 U.S.C. 5703.

HUD seeks highly qualified and motivated individuals who meet the requirements set forth in the Act to serve as voting members of the MHCC for up to two terms of three years. The MHCC expects to meet at least one to two times annually. Meetings may take place by conference call or in person. Members of the MHCC undertake additional work commitments on subcommittees and task forces regarding issues under deliberation.

Nominee Selection and Appointment

Members of the Consensus Committee are appointed to serve in one of three member categories. Nominees will be appointed to fill voting member vacancies in the following categories:

1. *Producers*—Seven producers or retailers of manufactured housing.

2. *Users*—Seven persons representing consumer interests, such as consumer organizations, recognized consumer leaders, and owners who are residents of manufactured homes.

3. *General Interest and Public Officials*—Seven general interest and public official members.

The Act provides that the Secretary shall ensure that all interests directly and materially affected by the work of the MHCC have the opportunity for fair and equitable participation without dominance by any single interest; and may reject the appointment of any one or more individuals in order to ensure that there is not dominance by any single interest. For purposes of this determination, dominance is defined as a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation.

Additional requirements governing appointment and member service include:

(1) Nominees appointed to the User category, and three of the individuals appointed to the General Interest and Public Official category shall not have a significant financial interest in any segment of the manufactured housing industry; or a significant relationship to any person engaged in the manufactured housing industry.

(2) Each member serving in the User category shall be subject to a ban disallowing compensation from the manufactured housing industry during the period of, and during the one year following, his or her membership on the MHCC.

(3) Nominees selected for appointment to the MHCC shall be required to provide disclosures and certifications regarding conflict-of-

interest and eligibility for membership prior to finalizing an appointment.

All selected nominees will be required to submit certifications of eligibility under the foregoing criteria as a prerequisite to final appointment.

Consensus Committee—Advisory Role

The MHCC's role is to advise the Secretary on the subject matter described above.

Federal Advisory Committee Act

The MHCC is subject to the requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix), 41 CFR parts 101–6 and 102–3 (the FACA Final Rule), and to the Presidential Memorandum, dated June 18, 2010, directing all heads of executive departments and agencies not to make any new appointments or reappointments of federally registered lobbyists to advisory committees and other boards and commissions. The June 18, 2010, Presidential Memorandum authorized the Director of the Office of Management and Budget (OMB) to issue guidance to implement this policy. On August 13, 2014 (79 FR 47482), OMB issued guidance regarding the prohibition against appointing or re-appointing federally registered lobbyists to clarify that the ban applies to persons serving on advisory committees, boards, and commissions in their individual capacity and does not apply if they are specifically appointed to represent the interests of a nongovernmental entity, a recognizable group of persons or nongovernmental entities (an industry sector, labor unions, environmental groups, etc.), or state or local governments.

Term of Office

Consensus Committee members serve at the discretion of the Secretary or for a three-year term and for up to two terms.

Nominee Information

Individuals seeking nomination to the MHCC should submit detailed information documenting their qualifications as addressed in the Act and this Notice. Individuals may nominate themselves. HUD recommends that the application form be accompanied by a resume.

Additional Information

The Department will make appointments from nominations submitted in response to this Notice. Also, individuals that applied last year do not need to re-apply; pursuant to this notice those applications are on file and may be considered for future appointments.

To be considered for appointment to a position of an MHCC member whose term expires in December of 2019, the nomination should be submitted by November 25, 2019.

Appointments will be made at the discretion of the Secretary.

Dated: October 18, 2019.

Brian D. Montgomery,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2019–23349 Filed 10–24–19; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7011–N–45]

30-Day Notice of Proposed Information Collection: Multifamily Default Status Report; OMB Control No.: 2502–0041

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* November 25, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Brian Murray, Acting Director, Office of Asset Management and Portfolio Oversight, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email *brian.a.murray@hud.gov* or telephone at (202) 402–2059. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comments on the information for a period of 60 days was published on April 26, 2019.

A. Overview of Information Collection

Title of Information Collection: Multifamily Default Status Report.

OMB Approval Number: 2502–0041.

OMB Expiration Date: 10/31/19.

Type of Request: Revision of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: The regulations at 24 CFR 207.256, 24 CFR 207.256a, and 24 CFR 207.258 require a mortgagee to notify HUD when a mortgage payment is in default (more than 30 days past due), when a mortgage has been reinstated, and to submit an election to assign a defaulted loan to HUD within a specified timeframe from the date of default. The regulation at 24 CFR 200, Subpart B, requires lenders to submit delinquency, default, election to assign, and other related loan information statuses electronically to HUD. Lenders previously used HUD Form 92426 for these submissions, however, with the implementation of the regulation requiring electronic notification, the Multifamily Delinquency and Default Reporting System (MDDR) was established to replace the paper form HUD–92426. HUD uses the information as an early warning mechanism to work with project owners and lenders to develop a plan that will reinstate a loan and avoid an insurance claim. It also provides HUD staff a mechanism for mortgagee compliance with HUD's loan servicing procedures and assignments.

Respondents (i.e., affected public): Respondents are FHA-approved multifamily lenders (business or other for-profit).

Estimated Number of Respondents: 114.

Estimated Number of Responses: 1368.

Frequency of Response: 12.

Average Hours per Response: .17.

Total Estimated Burden: 232.56.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(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 the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: October 17, 2019.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2019–23396 Filed 10–24–19; 8:45 a.m.]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7014–N–26]

60-Day Notice of Proposed Information Collection: Application for FHA Insured Mortgages

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* December 24, 2019.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, US Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov.* This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard. Copies of available documents submitted to OMB may be obtained from Ms. Pollard. Stakeholders may also view the proposed changes to the certification at: *https://www.hud.gov/program_offices/housing/sfh/SFH_policy_drafts.*

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Application for FHA Insured Mortgages.

OMB Approval Number: 2502–0059.

Type of Request: Revision of currently approved collection.

Form Number: HUD–92900–A, HUD–92900–B, HUD–92900–LT, HUD–92561, Model Notice for Informed Consumer Choice Disclosure, Model Pre-Insurance Review/Checklist, Settlement Certification (previously known as Addendum to HUD–1) and HUD–92544.

Description of the need for the information and proposed use: Specific forms and related documents are needed to determine the eligibility of the borrower and proposed mortgage transaction for FHA's insurance endorsement. The URLA and form HUD–92900–A (Addendum to the URLA) are used in every case by the lender to make application for FHA mortgage insurance. Together they describe the parties involved, the property, and the conditions and terms on which the mortgage insurance will be based. The form 92900–A was updated to: revise certifications to reflect regulations and other legal requirements; ensure accuracy of information provided to FHA; reduce uncertainty in the industry; maintain the ability to enforce FHA program requirements; and remove VA requirements and certifications from the 92900–A. Lenders seeking FHA's insurance prepare certain forms to collect data.

Respondents (*i.e.,* affected public): Individuals (loan applicants) and Business or other for-profit (lenders).

Estimated Number of Respondents: 15,871.

Estimated Number of Responses: 5,798,629.

Frequency of Response: One for each FHA-insured mortgage.

Average Hours per Response: 44 minutes (varies per form and type of loan).

Total Estimated Burdens: 692,542.

Attached as Appendix A is Form HUD–92900–A, HUD Addendum to Uniform Residential Loan Application, with changes for review and public comment.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(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 the burden of the proposed collection of information;

(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 through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: October 9, 2019.

John L. Garvin,

General Deputy Assistant Secretary for Housing.

BILLING CODE 4210–67–P

APPENDIX A - HUD Addendum to Uniform Residential Loan Application (DRAFT)

Part I - Identifying Information **HUD/FHA** Application for Insurance Under the National Housing Act and Borrower Certification	**FHA Case No.** (include any suffix)	**Mortgagee Case No.**
Mortgagee I.D.	**Sponsor I.D.**	**Agent I.D.**
Mortgagee Name, Address (include zip code) and Telephone Number Type or Print all entries clearly	**Name and Address of Sponsor**	**Name and Address of Agent**
Borrower's Name & Present Address (include zip code)	**Property Address** (include name of subdivision, lot & block no. & zip code)	

Sponsored Originations	**Name of Third-Party Originator**	NMLS ID of Third-Party Originator

Part II - Borrower Consent for Social Security Administration to Verify Social Security Number

I authorize the Social Security Administration (SSA) to verify my Social Security Number (SSN) to the Mortgagee and HUD/FHA through a computer match to be conducted by HUD/FHA, and to provide additional information or records pertaining to my SSN to HUD/FHA.

I understand that my consent allows no additional information or records pertaining to my SSN to be provided to the Mortgagee, and that verification of my SSN does not constitute confirmation of my identity. I also understand that my SSN or records pertaining thereto may not be used for any other purpose, including the resale or redisclosure to third parties, other than stated above. However, redisclosure to HUD/FHA may be permitted by this authorization to ensure that HUD/FHA complies with the SSA's requirements for disclosure of information and records. This consent is valid for 180 days from the date signed, unless indicated otherwise by the individual(s) named in this loan application.

Signature(s) of Borrower(s) - Read consent carefully. Review accuracy of Social Security number(s) provided on this application.

Borrower's Name: _____	Co-Borrower's Name: _____
Date of Birth: _____	Date of Birth: _____
Social Security Number: _____	Social Security Number: _____
Signature(s) of Borrower(s) Date Signed	Signature(s) of Co-Borrower(s) Date Signed
/	/ /

Part III - Borrower Notices, Information, and Acknowledgment

Public Reporting Burden

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless that collection displays a valid OMB control number, which can be located on the OMB Internet page at http://www.reginfo.gov/public/do/PRAMain.

Privacy Act Information

The information requested on the Uniform Residential Loan Application and this Addendum is authorized by the National Housing Act of 1934, 12 U.S.C. § 1701, et seq. The Debt Collection Act of 1982, Pub. L. 97-365, and HUD's Housing and Community Development Act of 1987, 42 U.S.C. § 3543, require persons applying for a federally insured loan to furnish their SSN. You must provide all the requested information, including your SSN. HUD may conduct a computer match to verify the information you provide. HUD may disclose certain information to Federal, State and local agencies when relevant to civil, criminal, or regulatory investigations and prosecutions. It will not otherwise be disclosed or released outside of HUD except as required and permitted by law. The information will be used to determine whether you qualify as a mortgagor. Failure to provide any of the requested information, including SSN, may result in disapproval of your loan application. This is notice to you as required by the Right to Financial Privacy Act of 1978 that HUD/FHA has a right of access to financial records held by financial institutions in connection with the consideration or administration of assistance to you. Financial records involving your transaction will be available to HUD/FHA without further notice or authorization but will not be disclosed or released by the institution to another Government Agency or Department without your consent except as required or permitted by law.

WARNING: This warning applies to all certifications made in this document.

Anyone who knowingly submits a false claim, or makes false statements is subject to criminal and civil penalties, including confinement for up to 5 years, fines, and civil penalties. 18 U.S.C. §§ 287, 1001 and 31 U.S.C. §3729

Caution: Delinquencies, Defaults, Foreclosures and Abuses

Delinquencies, defaults, foreclosures and abuses of mortgage loans involving programs of the Federal Government can be costly and detrimental to your credit, now and in the future. The Mortgagee in this transaction, its agents and assigns as well as the Federal Government, its agencies, agents and assigns are authorized to take any and all of the following actions in the event loan payments become delinquent on the mortgage loan described in the attached application: (1) Report your name and account information to a credit bureau; (2) Assess additional interest and penalty charges for the period of time that payment is not made; (3) Assess charges to cover additional administrative costs incurred by the Federal Government to service your account; (4) Offset amounts owed to you under other Federal programs; (5) Refer your account to a private attorney, collection agency or mortgage servicing agency to collect the amount due, foreclose the mortgage, sell the property and seek judgment against you for any deficiency; (6) Refer your account to the Department of Justice (DOJ) for litigation in the courts; (7) If you are a current or retired Federal employee, take action to offset your salary, or civil service retirement benefits; (8) Refer your debt to the Internal Revenue Service for offset against any amount owed to you as an income tax refund; and (9) Report any resulting written off debt of yours to the Internal Revenue Service as your taxable income. All of these actions may be used to recover any debts owed when it is determined to be in the interest of the Mortgagee or Federal Government, or both.

As a mortgage loan borrower, you will be legally obligated to make the mortgage payments called for by your mortgage loan contract. The fact that you dispose of your property after the loan has been made will not relieve you of liability for making these payments. Payment of the loan in full is ordinarily the way liability on a mortgage note is ended. Some home buyers have the mistaken impression that if they sell their homes when they move to another locality, or dispose of it for any other reasons, they are no longer liable for the mortgage payments and that liability for these payments is solely that of the new owners. Even through the new owners may agree in writing to assume liability for your mortgage payments, this assumption agreement will not relieve you from liability to the holder of the note which you signed when you obtained the loan to buy the property. Unless you are able to sell the property to a buyer who is acceptable to HUD/FHA who will assume the payment of your obligation to the lender, you will not be relieved from liability to repay any claim which HUD/FHA may be required to pay your lender on account of default in your loan payments. The amount of any such claim payment may be a debt owed by you to the Federal Government and subject to established collection procedures.

Fair Housing Act

I and anyone acting on my behalf are, and will remain, in compliance with the Fair Housing Act, 42 U.S.C. § 3604, et seq., with respect to the dwelling or property covered by the loan and in the provision of services or facilities in connection therewith. I recognize that any restrictive covenant on this property related to race, color, religion, sex, disability, familial status, or national origin is unlawful under the Fair Housing Act and unenforceable. I further recognize that in addition to administrative action by HUD, a civil action may be brought by the DOJ in any appropriate U.S. court against any person responsible for a violation of the applicable law.

Certification and Acknowledgment

All information in this application is given for the purpose of obtaining a loan to be insured under the National Housing Act and the information in the Uniform Residential Loan Application and this Addendum is true and complete to the best of my knowledge and belief. Verification may be obtained from any source named herein. I have read and understand the foregoing concerning my liability on the loan and Part III, Borrower Notices, Information and Acknowledgment.

Signature(s) of Borrower(s) - Do not sign unless this application is fully completed. Read the certification carefully and review accuracy of this application.

Signature(s) of Borrower(s)	Date Signed	Signature(s) of Co-Borrower(s)	Date Signed
	/ /		/ /

Borrower Name: _____ FHA Case No.: _____

Part IV - Direct Endorsement Approval for a HUD FHA-Insured Mortgage

A. Underwriting the Borrower

Date Mortgage Approved: _____ Date Approval Expires: _____

For mortgages rated as an "accept" or "approve" by FHA's TOTAL Mortgage Scorecard:

- The information submitted to TOTAL was documented in accordance with Single Family Housing Policy Handbook 4000.1 (SF Handbook) and accurately represents the final information obtained by the mortgagee; and
- This mortgage complies with SF Handbook 4000.1 Section II.A.4.e Final Underwriting Decision (TOTAL) to the extent that no defect exists in connection with the underwriting of this mortgage such that it should not have been approved in accordance with FHA requirements.

I certify that the statements above are materially correct, with the understanding that, in the event HUD elects to pursue a claim arising out of or relating to any inaccuracy of this certification, HUD will interpret the severity of such inaccuracy in a manner that is consistent with the HUD Defect Taxonomy in effect as of the date this mortgage is endorsed for insurance.

Mortgagee Representative Signature: _____

Printed Name: _____

Title: _____

- - - - - - - - - - OR - - - - - - - - - - - - -

For mortgages rated as a "refer" by FHA's TOTAL Mortgage Scorecard, or manually underwritten by a Direct Endorsement underwriter:

- I have personally reviewed and underwritten the borrower's credit application;
- The information used to underwrite borrower was documented in accordance with Single Family Housing Policy Handbook 4000.1 (SF Handbook) and accurately represents the final information obtained by the mortgagee; and
- This mortgage complies with SF Handbook 4000.1 Section II.A.5.d Final Underwriting Decision (Manual)) to the extent that no defect exists in connection with the underwriting of this mortgage such that it should not have been approved in accordance with FHA requirements.

I certify that the statements above are materially correct, with the understanding that in the event HUD elects to pursue a claim arising out of or relating to any inaccuracy of this certification, HUD will interpret the severity of such inaccuracy in a manner that is consistent with the HUD Defect Taxonomy in effect as of the date this mortgage is endorsed for insurance.

Direct Endorsement Underwriter Signature: _____ DE's ID Number: _____

B. Underwriting the Property

For all mortgages where FHA requires an appraisal, I have personally reviewed and underwritten the appraisal according to FHA requirements. I certify that the statements above are materially correct, with the understanding that in the event HUD elects to pursue a claim arising out of or relating to any inaccuracy of this certification, HUD will interpret the severity of such inaccuracy in a manner that is consistent with the HUD Defect Taxonomy in effect as of the date this mortgage is endorsed for insurance.

Direct Endorsement Underwriter Signature: _____DE's ID Number: _____

Part V. Mortgagee's Certification

- I have personally reviewed the mortgage documents and the application for insurance endorsement;
- This mortgage complies with SF Handbook 4000.1 Section II.A.7 Post-Closing and Endorsement to the extent that no defect exists that would have changed the decision to endorse or submit the mortgage for insurance.

I certify that the statements above are materially correct, with the understanding that in the event HUD elects to pursue a claim arising out of or relating to any inaccuracy of this certification, HUD will interpret the severity of such inaccuracy in a manner that is consistent with the HUD Defect Taxonomy in effect as of the date this mortgage is endorsed for insurance.

Mortgagee	
Name of Mortgagee's Representative	
Title of Mortgagee's Representative	
Signature of the Mortgagee's Representative	Date

[FR Doc. 2019–23240 Filed 10–24–19; 8:45 am]
BILLING CODE 4210–67–C

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2019–N094; FXES11130100000–190– FF01E00000]

Endangered and Threatened Wildlife and Plants; Draft Amendment to the Recovery Plan for the Rough Popcornflower

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comment.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft amendment updating the recovery criteria in the Recovery Plan for the Rough Popcornflower (*Plagiobothrys hirtus*). Rough popcornflower, listed as endangered under the Endangered Species Act (ESA), is an annual herb in the borage family (Boraginaceae), endemic to wet swales and meadows in Douglas County, Oregon. We are updating recovery criteria to better assist in determining when the species has recovered to the point that it may be reclassified as threatened, or that the protections afforded by the ESA are no longer necessary and the species may be removed from the ESA's protections. We request review of this draft recovery plan amendment and invite comments from local, State, Tribal, and Federal agencies, nongovernmental organizations, and the public.

DATES: To ensure consideration, we must receive written comments on or before November 25, 2019. However, we will accept information about the species at any time.

ADDRESSES: *Reviewing documents:* If you wish to review the draft recovery plan amendment, you may obtain copies on our website, at *https://ecos.fws.gov/docs/recovery_plan/Draft_Amendment_Rough_Popcornflower_Recovery_Plan_2019.pdf.* You may also request copies of the draft recovery plan amendment by contacting Michele Zwartjes at the U.S. mail or email address below.

Submitting comments: If you wish to comment, submit your comments by one of the following methods:

1. *U.S. Mail or Hand-Delivery:* You may submit written comments and materials to Field Supervisor, Attention: Rough Popcornflower Recovery Plan Amendment, Oregon Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2600 SE 98th Ave., Suite 100, Portland, OR 97266; or

2. *Email:* You may send comments by email to *fw1ofwo@fws.gov.* Please include "Rough Popcornflower Draft Recovery Plan Amendment Comments" in the subject line.

FOR FURTHER INFORMATION CONTACT: Michele Zwartjes, Recovery Coordinator, at the above Oregon Fish and Wildlife Office mailing address and email, or by telephone at 503–231–6179. Individuals who are hearing impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

We, the U.S. Fish and Wildlife Service (Service), announce the

availability of a draft recovery plan amendment, which updates recovery criteria for the rough popcornflower.

Recovery of endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of our endangered species program and the ESA. Recovery means improvement of the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the ESA. The ESA requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species.

The purpose of a recovery plan is to provide a feasible and effective roadmap for a species' recovery, with the goal of improving its status and managing its threats to the point at which protections under the ESA are no longer needed. Recovery plans must be designed so that all stakeholders and the public understand the rationale behind the recovery program, whether they were involved in writing the plan or not, and recognize their role in its implementation. We are requesting submission of any information that enhances the necessary understanding of the species' biology and threats and its recovery needs and related implementation issues or concerns, to ensure that we have assembled, considered, and incorporated the best available scientific and commercial information into the draft recovery plan amendment.

Recovery plans provide important guidance to the Service, States, other partners, and the general public on methods of minimizing threats to listed species and objectives against which to measure the progress towards recovery; they are guidance and not regulatory documents. A recovery plan identifies, organizes, and prioritizes recovery actions and is an important guide that ensures sound scientific decision-making throughout the recovery process, which can take decades.

Recovery Plan Amendment

Keeping recovery plans current ensures that threatened species and endangered species benefit through timely partner-coordinated implementation of recovery actions.

A review of a recovery plan and its implementation may show that the plan is out of date or that the plan's usefulness is limited and the plan warrants modification. The need for, and extent of, recovery plan modifications will vary considerably among recovery plans, depending on the scope and complexity of the initial plan, the structure of the document, and the involvement of stakeholders. Recovery plan modifications can range from relatively minor updates to a substantial rewrite that revises the existing plan in part (*i.e.,* an amendment to one of the sections that modifies the existing plan), or in full (*i.e.,* a full revision that completely replaces the existing plan). The need for a recovery plan amendment or revision may be triggered when, among other possibilities: (1) New information has been identified, such as population-level threats to the species or previously unknown life-history traits, which necessitates new or revised recovery strategy, actions, or criteria, or revision of all three in order to maintain the adequacy of the plan; and (2) the current plan is not achieving its objectives. Amendments and revisions benefit endangered and threatened species, our partners, and the public by keeping recovery plans consistent with current information about what is needed for species' recovery.

Substantive amendment of recovery plans requires public notice and comment under section 4(f)(4) of the ESA, including: (1) A **Federal Register** notice of availability to give opportunity for public review and comment, (2) consideration of all information presented during the public comment period, and (3) approval by the Regional Director. When finalized, this recovery plan amendment will be made publicly available on the internet through our Environmental Conservation Online System (ECOS, *https://ecos.fws.gov*).

Recovery Plan for Rough Popcornflower

The Service approved a recovery plan for rough popcornflower in 2003; however, the original plan did not establish criteria for removing rough popcornflower from the Federal List of Endangered and Threatened Plants (delisting).

Since the publication of the recovery plan in 2003, new information has been gathered on the species' biology, distribution, and threats, leading us to propose modifiying the original downlisting criteria (reclassifying rough popcornflower from endangered to threatened status) and to develop new delisting criteria. Therefore, this document describing these criteria will serve as a draft amendment to the 2003 recovery plan.

The recovery criteria established in a recovery plan (such as those proposed in this draft recovery plan amendment) will serve as an indicator that a review of the species' status is advisable, and we may consider downlisting, or if appropriate, removal from the Federal List of Endangered and Threatened Plants following a five factor analysis in accordance with section 4(a)(1) of the ESA.

Request for Public Comments

Section 4(f) of the ESA requires us to provide public notice and an opportunity for public review and comment during recovery plan development. It is also our policy to request peer review of recovery plans (July 1, 1994; 59 FR 34270). In an appendix to the approved recovery plan amendment, we will summarize and respond to the issues raised by the public and peer reviewers. Substantive comments may or may not result in changes to the recovery plan; comments regarding recovery plan implementation will be forwarded as appropriate to Federal or other entities so that they can be taken into account during the course of implementing recovery actions. Responses to individual commenters will not be provided, but we will provide a summary of how we addressed substantive comments in an appendix to the approved recovery plan amendment.

We invite written comments on the draft recovery plan amendment. In particular, we are interested in additional information regarding the current threats to the species, ongoing beneficial management efforts, and the costs associated with implementing the recommended recovery actions.

Public Availability of Comments

All comments received, including names and addresses, will become part of the administrative record and will be available to the public. 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—will be publicly available. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Comments and materials we receive will be available, by appointment, for public inspection during normal business hours at our office (see **ADDRESSES**).

Authority

The authority for this action is section 4(f) of the Endangered Species Act (16 U.S.C. 1533 (f)).

Dated: August 8, 2019.

Robyn Thorson,

Regional Director, Pacific Region.

[FR Doc. 2019–23317 Filed 10–24–19; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–29080; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before October 5, 2019, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by November 12, 2019.

ADDRESSES: Comments may be sent via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C St. NW, MS 7228, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before October 5, 2019. Pursuant to Section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

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.

Nominations submitted by State Historic Preservation Officers:

ALABAMA

Fayette County

Mitchell Farmstead, US 43, W side, 46 mi. N of Harbin Rd., Bobo vicinity, SG100004617

Jefferson County

Five Points South Historic (District Boundary Increase III), Generally bounded by 10th Ave. S, 21st Pl. S, 15th Ave. S & 17th St. S, Birmingham, BC100004615

Birmingham Food Terminal Historic District, Finley Ave. W between 3rd Pl. W and 1st St. W, Birmingham, SG100004619

South Central Bell Building, 600 19th St. N, Birmingham, SG100004626

Morgan County

Crabb-Stewart-Key House, 1084 Nat Key Rd., Hartselle vicinity, SG100004618

COLORADO

Denver County

Tammen Hall, 1010 E 19th Ave., Denver, SG100004612

Larimer County

Kelley House, 1410 N Garfield Ave., Loveland, SG100004613

Las Animas County

Our Lady of Guadalupe Church and Medina Cemetery, CO Hwy. 12, Medina Plaza, SG100004628

Weld County

Star Filling Station, 301 Centre Ave., New Raymer, SG100004614

ILLINOIS

Hancock County

Hunziker Winery Site, Address Restricted, Warsaw, SG100004624

MISSOURI

Cooper County

Phoenix American Cob Pipe Factory, 2nd & Vine Sts., Boone, SG100004604

Jackson County

Hoover Brothers Building, 922 Oak St., Kansas City, SG100004600

Crown Center Historic District, Bounded by Main St., Pershing Rd., 27th St., McGee St., Trfy, Grand Blvd., Kansas City, SG100004601

St. Charles County

Hausam, Peter, House, 1219 S Main St., St. Charles, SG100004599

St. Francois County

Howlett Gulf, 10 E Main St., Park Hills, SG100004602

St. Louis County

Maplewood Historic Commercial District, 7145–7233 & 7146–7192 Manchester Blvd., 7209–11 Lanham, Maplewood, SG100004603

NEBRASKA

Dawson County

Temple, Harry V., House, 305 E 13th St., Lexington, SG100004608

Douglas County

Omaha Auto Row Historic District (Lincoln Highway in Nebraska MPS), Roughly bounded by Douglas St., Dewey St., S 24th Ave. & S 28th St., Omaha, MP100004607

Red Willow County

Camp Indianola, E side of Cty. Rd. 396, 1.5 mi. N of Indianola, Indianola vicinity, SG100004609

OREGON

Multnomah County

Fried-Durkheimer House, 2177 SW Broadway Dr., Portland, SG100004606

SOUTH DAKOTA

Beadle County

Jefferson School (Schools in South Dakota MPS), 855 Utah Ave. SE, Huron, MP100004620

Haakon County

Midland Depot, 400 blk. of Main St., Midland, SG100004621

Spink County

Doland Commercial Historic District, Humphrey Dr. to 2nd St., Doland, SG100004622

WASHINGTON

Douglas County

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1235 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan, Highlands MPS), Address Restricted, Palisades vicinity, MP100004630

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1236 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan, Highlands MPS), Address Restricted, Palisades vicinity, MP100004631

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1237 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan, Highlands MPS), Address Restricted, Palisades vicinity, MP100004632

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1238 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan, Highlands MPS), Address Restricted, Palisades vicinity, MP100004633

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1239 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan, Highlands MPS), Address Restricted, Palisades vicinity, MP100004634

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1240 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan, Highlands MPS), Address Restricted, Palisades vicinity, MP100004635

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1241 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan, Highlands MPS), Address Restricted, Palisades vicinity, MP100004636

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1242 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan, Highlands MPS), Address Restricted, Palisades vicinity, MP100004637

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1243 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan,

Highlands MPS), Address Restricted, Palisades vicinity, MP100004638

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1244 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan, Highlands MPS), Address Restricted, Palisades vicinity, MP100004639

Southern Columbia Plateau and Okanogan Highlands Site No. 45DO1245 (Spiritually Significant Rock Features of the Southern Columbia Plateau and Okanogan, Highlands MPS), Address Restricted, Palisades vicinity, MP100004640

WISCONSIN

Bayfield County

THOMAS FRIANT shipwreck (gill net tug) (Great Lakes Shipwreck Sites of Wisconsin MPS), Address Restricted, Port Wing vicinity, MP100004627

In the interest of preservation, a shortened comment period has been requested for the following resource:

OHIO

Franklin County

Standard Building, The, 174 E Long St., Columbus, SG100004597, Comment period: 3 days

An additional documentation has been received for the following resource:

ALABAMA

Jefferson County

Five Points South Historic District, Roughly bounded by 10th and 15th Aves., 19th and 21st Sts., Birmingham, AD83002973

ILLINOIS

Cook County

Uptown Square Historic District, Roughly along Lawrence Ave., and Broadway, Chicago, AD00001336

Authority: Section 60.13 of 36 CFR part 60.

Dated: October 7, 2019.

Julie H. Ernstein,

Supervisory Archeologist, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2019–23354 Filed 10–24–19; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[Docket No. BOEM–0071]

Guidelines for Providing Information on Lighting and Marking of Structures Supporting Renewable Energy Development

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: Notice of availability of Draft Proposed Guidelines for Providing Information on Lighting and Marking of Structures Supporting Renewable Energy Development.

SUMMARY: BOEM's Office of Renewable Energy Programs (OREP) is making available for public review its Draft Proposed Guidelines for Providing Information on Lighting and Marking of Structures Supporting Renewable Energy Development on the Outer Continental Shelf (OCS) and is inviting public comment on how they might be improved. The guidelines may be accessed at *https://www.boem.gov/National-and-Regional-Guidelines-for-Renewable-Energy-Activities/.*

DATES: Stakeholders and interested parties may submit comments electronically or by regular mail, postmarked no later than November 25, 2019. OREP is also offering a web-based presentation on this subject on November 20, 2019, which may be accessed at *http://www.boem.gov/Regulatory-Framework.*

ADDRESSES: Comments should be submitted in one of the two following ways:

1. *Electronically: http://www.regulations.gov.* In the entry entitled, ''Enter Keyword or ID,'' search for BOEM–2019–0071. Follow the instructions to submit public comments in response to this document.

2. *Written Comments:* Mail to: Bureau of Ocean Energy Management, Office of Renewable Energy Programs, 45600 Woodland Road, VAM–OREP, Sterling, Virginia 20166. Please include your name, return address, and phone number or email address, so we can contact you if we have questions regarding your submission.

Public Availability of Comments: Before including your address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. In order for BOEM to withhold from disclosure your personally identifiable information, you must identify any information contained in the submittal of your comments that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequences of the disclosure of information, such as embarrassment, injury, or other harm. While you can ask us in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

FOR FURTHER INFORMATION CONTACT: Angel McCoy, *angel.mccoy@boem.gov,* or by mail at: Bureau of Ocean Energy Management, Office of Renewable Energy Programs, 45600 Woodland Road, VAM–OREP, Sterling, Virginia 20166, (703) 787–1758.

SUPPLEMENTARY INFORMATION:

Authority: This notice is published pursuant to subsection 8(p) of the OCS Lands Act (43 U.S.C. 1337(p)), added by Section 388 of the Energy Policy Act of 2005, and the implementing regulations at 30 CFR 585.116. This regulatory provision states that the Director, ''may . . . solicit information from industry and other relevant stakeholders (including state and local agencies), as necessary, to evaluate the state of the offshore renewable energy industry, including the identification of potential challenges or obstacles to its continued development.''

Purpose: BOEM is seeking public comment on its Draft Proposed Guidelines for Providing Information on Lighting and Marking of Structures Supporting Renewable Energy Development on the OCS. In particular, BOEM is seeking comment on whether these draft proposed guidelines set forth appropriate recommendation and/or are necessary given applicable international standards and practices.

The BOEM Office of Renewable Energy Programs (OREP) drafted these guidelines based upon studies and consultations with the Federal Aviation Administration (FAA) and United States Coast Guard (USCG). In response to stakeholder comments and concerns, BOEM convened a working group of Federal agencies with interests in lighting, including the FAA, USCG, Department of Defense (DoD), National Park Service, United States Fish and Wildlife Service, and the Bureau of Safety and Environmental Enforcement. The working group noted the absence of FAA regulations or guidance regarding the use of lighting for offshore wind turbines beyond the United States Territorial Sea, 12 nm (22.2 km) offshore.

In addition, BOEM funded the study *Development of Guidance for Lighting of Offshore Wind Turbines Beyond 12 Nautical Miles* (BOEM OCS Study 2016–002, *https://www.boem.gov/offshore-lighting-guidance/*). The study analyzed FAA guidance (Advisory Circular AC 70/7460–1, Chapter 13) and identified best management practices related to aviation safety while addressing environmental concerns identified in BOEM OCS Study 2013–0116. This guidance incorporates conclusions of the 2016 study and recommendations from the working group.

These draft proposed guidelines contain recommendations for industry to follow and also summarize the relevant FAA and USCG regulatory requirements on lighting and marking design for wind energy facilities on Federal renewable energy leases on the OCS. The draft proposed guidelines outline the types of information that BOEM requests from lessees as part of their Site Assessment Plan (SAP), Construction and Operations Plan (COP), or General Activities Plan (GAP), as applicable. BOEM's goal is to ensure that the lighting and marking of offshore wind energy facilities:

- Are safe;
- do not unreasonably interfere with other uses of the OCS;
- do not cause undue harm or damage to natural resources; life (including human and wildlife); property; the marine, coastal, or human environment; or sites, structures, or objects of historical or archaeological significance;
- use best available and safest technology; and
- use best management practices.

These recommendations are offered to assist lessees in demonstrating that their SAPs, COPs or GAPs adequately address the concerns enumerated above. This draft proposed guidance is not intended to set information or data standards or prescribe additional regulatory requirements. Even under the draft proposed guidance, lessees would remain free to propose alternative design parameters to provide for aviation safety, avoid harm to wildlife, avoid interference with other users, and/or further other criteria for plan approval.

For more information about BOEM's renewable energy program, please visit: *http://www.boem.gov/Renewable-Energy/.*

Protection of Privileged or Confidential Information: BOEM will protect privileged or confidential information that you submit as required by the Freedom of Information Act (FOIA). Exemption 4 of FOIA applies to trade secrets and commercial or financial information that you submit that is privileged or confidential. If you wish to protect the confidentiality of such information, clearly mark it and request that BOEM treat it as confidential. BOEM will not disclose such information, except as required by FOIA. Please label privileged or confidential information ''Contains Confidential Information'' and consider submitting such information as a separate attachment.

However, BOEM will not treat as confidential any aggregate summaries of such information or comments not containing such information. Additionally, BOEM may not treat as confidential the legal title of the commenting entity (*e.g.,* the name of your company). Information that is not labeled as privileged or confidential will be regarded by BOEM as suitable for public release.

Dated: October 21, 2019.

Walter D. Cruickshank,

Acting Director, Bureau of Ocean Energy Management.

[FR Doc. 2019–23248 Filed 10–24–19; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Control Number 1010–0048; Docket ID: BOEM–2017–0016]

Agency Information Collection Activities; 30 CFR 551, Geological and Geophysical Explorations of the Outer Continental Shelf

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Ocean Energy Management (BOEM) is proposing to renew an information collection request (ICR) with revisions.

DATES: Interested persons are invited to submit comments on or before December 24, 2019.

ADDRESSES: Send your comments on this ICR by mail to the BOEM Information Collection Clearance Officer, Anna Atkinson, Bureau of Ocean Energy Management, 45600 Woodland Road, Sterling, Virginia 20166; or by email to *anna.atkinson@boem.gov.* Please reference OMB Control Number 1010–0048 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Anna Atkinson by email, or by telephone at 703–787–1025.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, BOEM provides the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps BOEM assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

BOEM is soliciting comments on the proposed ICR described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of BOEM; (2) what can BOEM do to ensure that this information be processed and used in a timely manner; (3) is the burden estimate accurate; (4) how might BOEM enhance the quality, utility, and clarity of the information to be collected; and (5) how might BOEM minimize the burden of this collection on the respondents, including minimizing the burden through the use of information technology?

Comments submitted in response to this notice are a matter of public record. BOEM will include or summarize each comment in our request to the Office of Management and Budget (OMB) for approval of this ICR. You should be aware that your entire comment—including your address, phone number, email address, or other personally identifiable information—may be made publicly available at any time. In order for BOEM to withhold from disclosure your personally identifiable information, you must identify any information contained in the submittal of your comments that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequences of the disclosure of information, such as embarrassment, injury, or other harm. While you can ask us in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

BOEM protects proprietary information in accordance with the Freedom of Information Act (5 U.S.C. 552) and the Department of the Interior's implementing regulations (43 CFR part 2), and under applicable sections of 30 CFR part 551 promulgated pursuant to Outer Continental Shelf Lands Act (OCSLA) at 43 U.S.C. 1352(c).

Abstract: Section 11(g) of the OCSLA, as amended (43 U.S.C. 1340(g)), authorizes the Secretary of the Interior to prescribe rules and regulations to govern the issuance of permits for geological exploration on the Outer Continental Shelf (OCS). The OSCLA at 43 U.S.C. 1340 states that ''any person authorized by the Secretary may conduct geological and geophysical explorations in the [O]uter Continental Shelf, which do not interfere with or endanger actual operations under any lease maintained or granted pursuant to this subchapter, and which are not unduly harmful to aquatic life in such

area.'' The section further provides that permits to conduct such activities may be issued only if it is determined that: The applicant is qualified; the activities will not interfere with or endanger operations under any lease issued or maintained pursuant to OCSLA; and the activities will not be unduly harmful to aquatic life, result in pollution, create hazardous or unsafe conditions, unreasonably interfere with other uses of the area, or disturb any site, structure, or object of historical or archaeological significance.

Applicants for permits are required to submit Form BOEM–0327 to provide the information necessary to evaluate their qualifications, and upon approval, respondents are issued a permit. Once an application is reviewed and approved, a permit (Form BOEM–0328 and Form BOEM–0329) is signed by BOEM and the permittee.

The Independent Offices Appropriations Act (31 U.S.C. 9701), the Omnibus Appropriations Bill (Pub. L. 104–133, 110 Stat. 1321, April 26, 1996), and OMB Circular A–25 authorize Federal agencies to recover the full cost of services that confer special benefits. All geological and geophysical permits are subject to cost recovery, and BOEM regulations specify service fees for these requests.

Regulations to carry out these responsibilities are contained in 30 CFR part 551 and are the subject of this information collection renewal. BOEM uses the information to:

- Identify oil, gas, sulfur, and mineral resources in the OCS;
- Ensure the receipt of fair value for mineral resources;
- Ensure that the exploration activities do not cause harm to the environment or persons, or create unsafe operations and conditions, damage historical or archaeological sites, or interfere with other uses;
- Analyze and evaluate preliminary or planned drilling activities;
- Monitor progress and activities in the OCS;
- Acquire geological and geophysical data and information collected under a Federal permit offshore; and
- Determine eligibility for reimbursement from the government for certain costs.

In this renewal, BOEM is renewing Form BOEM–0327—Requirements for Geological or Geophysical Explorations or Scientific Research on the Outer Continental Shelf. This form consists of the requirements for geological and geophysical activities requiring Permits and Notices, along with the application that the respondent submits to BOEM for approval, as well as a nonexclusive use agreement for scientific research, if applicable.

Upon BOEM approval of the application, respondents are issued a permit using Form BOEM–0328, Permit for Geophysical Exploration for Mineral Resources or Scientific Research on the Outer Continental Shelf, for conducting geophysical exploration for mineral resources or scientific research, or Form BOEM–0329, Permit for Geological Exploration for Mineral Resources or Scientific Research on the Outer Continental Shelf, for conducting geological exploration for mineral resources or scientific research. These permits are filled in by BOEM and do not incur a respondent hour burden. However, BOEM plans to revise these permits to include additional language. The modifications to the permits will allow BOEM to request the geological and geophysical data prior to the permittee deleting or removing the data from records, but still provides the option for the permittee to no longer maintain the data after ten years. The following describes the proposed changes:

- Form BOEM–0328 would include additional language in Section IV Paragraph (A) stating:

''*After a period of 10 years from the issuance of the permit, the permittee must notify the Supervisor in writing if their intention is to no longer maintain all or part of the geophysical data, processed geophysical information, and interpreted geophysical information, and provide the Supervisor 30 days to request that the permittee submit for inspection and possible retention all or part of the geophysical data, processed geophysical information, and interpreted geophysical information.*''

- Form BOEM–0329 would include additional language in Section VI Paragraph (A) stating:

''*After a period of 10 years from the issuance of the permit, the permittee must notify the Supervisor in writing if their intention is to no longer maintain all or part of the geological data, analyzed geological information, processed geological information, and interpreted geological information, and provide the Supervisor 30 days to request that the permittee submit for inspection and possible retention all or part of the geological data, analyzed geological information, processed geological information, and interpreted geological information.*''

Title of Collection: 30 CFR 551, Geological and Geophysical Explorations of the OCS.

OMB Control Number: 1010–0048.

Form Number: BOEM–0327, Requirements for Geological or Geophysical Explorations or Scientific Research on the Outer Continental Shelf.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Potential respondents comprise Federal OCS oil, gas, and sulfur permittees or notice filers.

Total Estimated Number of Annual Responses: 688 responses.

Total Estimated Number of Annual Burden Hours: 35,254 hours.

Respondent's Obligation: Mandatory.

Frequency of Collection: On occasion, annual, or as specified in permit.

Total Estimated Annual Non-hour Burden Cost: $136,816.

Estimated Reporting and Recordkeeping Hour Burden: The currently approved OMB paperwork burden is 35,254 annual burden hours, and will remain the same.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: October 21, 2019.

Deanna Meyer-Pietruszka,

Chief, Office of Policy, Regulation, and Analysis.

[FR Doc. 2019–23247 Filed 10–24–19; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF JUSTICE

Membership of the Senior Executive Service and Senior Level Standing Performance Review Boards

AGENCY: Department of Justice.

ACTION: Notice of Department of Justice's standing members of the Senior Executive Service and Senior Level Performance Review Boards.

Pursuant to the requirements of 5 U.S.C. 4314(c)(4), the Department of Justice announces the membership of its 2019 Senior Executive Service (SES) and Senior Level (SL) Standing Performance Review Boards (PRBs). The purpose of a PRB is to provide fair and impartial review of SES/SL performance appraisals, executive development plans, and award recommendations/pay adjustments.

The PRBs will make recommendations regarding the final performance ratings to be assigned, SES/SL awards and/or pay adjustments to be awarded.

FOR FURTHER INFORMATION CONTACT: Mary A. Lamary, Director, Human

Resources, Justice Management Division, Department of Justice, Washington, DC 20530; (202) 514–4350.

Lee J. Lofthus,

Assistant Attorney General for Administration.

2019 FEDERAL REGISTER

Name	Position title
Office of the Attorney General—OAG	
HAMILTON, GENE	COUNSELOR TO THE ATTORNEY GENERAL.
RABBITT, BRIAN	CHIEF OF STAFF AND ADVISOR OF WHITE COLLAR CRIMES/FINANCIAL MATTERS.
TUCKER, RACHEL	COUNSELOR TO THE ATTORNEY GENERAL.
SHEA, TIMOTHY	COUNSELOR TO THE ATTORNEY GENERAL.
BISSEX, RACHEL	GENERAL ATTORNEY (WHITE HOUSE LIAISON AND ADVISOR TO THE ATTORNEY GENERAL).
MORRISSEY, BRIAN	COUNSELOR TO THE ATTORNEY GENERAL.
LEVI, WILLIAM	COUNSELOR TO THE ATTORNEY GENERAL.
MORAN, JOHN	DEPUTY CHIEF OF STAFF AND COUNSELOR TO THE ATTORNEY GENERAL.
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GUAHAR, TASHINA	ASSOCIATE DEPUTY ATTORNEY GENERAL.
HUGHES, WILLIAM	ASSOCIATE DEPUTY ATTORNEY GENERAL.
HOVAKIMIAN, PATRICK	CHIEF OF STAFF/DIR CTOC/ADAG.
CONNOLLY, ROBERT	DIRECTOR, OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION.
GOLDSMITH, ANDREW	NATIONAL CRIMINAL DISCOVERY COORDINATOR.
MICHALIC, MARK	EMERGENCY PREPAREDNESS AND CRISIS RESPONSE COORDINATOR.
MASLING, MARK	CHIEF AND COUNSELOR, DEPUTY ATTORNEY GENERAL.
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Office of Privacy and Civil Liberties	
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Antitrust Division—ATR	
NIGRO, BERNARD	PRINCIPAL DEPUTY ASSISTANT ATTORNEY GENERAL.
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GREER, TRACY	ATTORNEY ADVISOR.
CONRATH, CRAIG	DIRECTOR OF LITIGATION.
AUGUSTINE, RENE	SENIOR COUNSEL.
DANKS, RYAN	CHIEF, NATIONAL CRIMINAL ENFORCEMENT SECTION.
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SCHEELE, SCOTT A	CHIEF, TELECOMMUNICATIONS AND MEDIA ENFORCEMENT SECTION.
O'NEILL, KATHLEEN S	SR DIR OF INVESTIGATION & LITIGATION.
HOAG, AARON	CHIEF, NETWORKS AND TECHNOLOGY ENFORCEMENT SECTION.
KENDLER, OWEN	CHIEF, LITIGATION III SECTION.
MARSHALL, LYNDA	CHIEF, FOREIGN COMMERCE SECTION.

2019 FEDERAL REGISTER—Continued

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DURASTANTI, JOHN	DEPUTY ASSISTANT DIRECTOR, FIELD OPERATIONS (PROGRAMS).
LAUDER, GEORGE	DEPUTY ASSISTANT DIRECTOR, FIELD OPERATIONS—CENTRAL.
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BEASLEY, ROGER	CHIEF INFORMATION OFFICER (CIO).
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EPSTEIN, ERIC	ATTORNEY ADVISOR.
MCDANIEL, MASON	SENIOR INFORMATION TECHNOLOGY SPECIALIST (CHIEF TECHNOLOGY OFFICER).
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VANDERPLOW, PAUL	SPECIAL AGENT IN CHARGE (SPECIAL OPERATIONS DIVISION).
BOARD JR., DANIEL	ASSISTANT DIRECTOR, OFFICE OF PUBLIC AND GOVERNMENTAL AFFAIRS.
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SAWYER, KATHLEEN	DIRECTOR (CORRECTIONAL PROGRAM OFFICER).
KANE, THOMAS	DEPUTY DIRECTOR (CORRECTIONAL PROGRAM OFFICER).
GRIFFITH, L. CRISTINA	ASSISTANT DIRECTOR, HUMAN RESOURCES MANAGEMENT DIVISION.
YEICH, KENNETH	SENIOR DEPUTY ASSISTANT DIRECTOR, FEDERAL PRISON INDUSTRIES.
O'CONNOR, PATRICK	CHIEF EXECUTIVE OFFICER (SUPVY. INDL. SPECLST).
GROSS, BRADLEY T	ASSISTANT DIRECTOR, ADMINISTRATION DIVISION.
BURNS, LONERYL C	SENIOR DEPUTY ASSISTANT DIRECTOR, ADMINISTRATION DIVISION.
AYERS, NANCY	CHIEF, OFFICE OF PUBLIC AFFAIRS.
GARRETT, JUDITH	CORRECTIONAL PROGRAM OFFICER (SPECIAL ASSISTANT).
THOMPSON, SONYA	SENIOR DEPUTY ASSISTANT DIRECTOR, INFORMATION, POLICY/PUBLIC AFFAIRS DIVISION.
HYLE, KENNETH	ASSISTANT DIRECTOR, OFFICE OF GENERAL COUNSEL.
KENDALL, PAUL F	SENIOR COUNSEL, OFFICE OF GENERAL COUNSEL.
RODGERS, RONALD L	SENIOR COUNSEL, OFFICE OF GENERAL COUNSEL.
ENGLISH, NICOLE	ASSISTANT DIRECTOR (CORRECTIONAL PROGRAM OFFICER).
WILLS, JAMES C	SENIOR DEPUTY COUNSEL, OFFICE OF GENERAL COUNSEL.

2019 FEDERAL REGISTER—Continued

Name	Position title
BROWN JR., ROBERT M	SENIOR DEPUTY DIRECTOR, NATIONAL INSTITUTE OF CORRECTIONS.
SHINN, DAVID	ASSISTANT DIRECTOR (CORRECTIONAL PROGRAM OFFICER).
HURWITZ, HUGH J	ASSISTANT DIRECTOR, RE-ENTRY SERVICES DIVISION.
QUINTANA, FRANCISCO J	WARDEN, FMC, LEXINGTON, KY.
BARNHART, JONATHAN	WARDEN, FCI, MANCHESTER, KY.
KIZZIAH, GREGORY	WARDEN, USP, MCCREARY, KY.
RASKIN, MINA	SENIOR DEPUTY ASSISTANT DIRECTOR, PROGRAMS REVIEW DIVISION.
FINLEY, SCOTT	WARDEN, FCI, SCHUYLKILL, PA.
YOUNG, DAVID L.	WARDEN, FCI, BECKLEY, WV.
WERLICH, THOMAS	WARDEN, FCI, GREENVILLE, IL.
HUDSON JR., DONALD J	WARDEN, FCI, THOMSON, IL.
KRUEGER, JEFFREY	CORRECTIONAL PROGRAM OFFICER (REGIONAL DIRECTOR).
HUDSON JR., DONALD J	WARDEN, USP, LEAVENWORTH, KS.
KALLIS, STEVEN	WARDEN, FMC, ROCHESTER, MN.
ORMOND, JOHNATHAN	REGIONAL DIRECTOR, NORTHEAST REGION.
HARMON, DARRIN	REGIONAL DIRECTOR, MID-ATLANTIC REGION.
YOUNG, WILLIAM S	WARDEN, FCI, FAIRTON, NJ.
ORTIZ, DAVID	WARDEN, FCI, FORT DIX, NJ.
QUAY, HERMAN	WARDEN, MDC, BROOKLYN, NY.
EBBERT, DAVID W	WARDEN, USP, LEWISBURG, PA.
CHEATHAM, ROY	COMPLEX WARDEN (CORRECTNL. INST. ADMR), COLEMAN, FL.
BEASLEY, GENE	CORRECTIONAL PROGRAM OFFICER (REGIONAL DIRECTOR), WESTERN REGION.
FOX, JOHN B	WARDEN, FTC, OKLAHOMA CITY, OK.
UPTON, JODY R	WARDEN, FMC, CARSWELL, TX.
WILSON, ERIC D	WARDEN, FCI, FORT WORTH, TX.
WITHERS, SHANNON	WARDEN, FCI, MARIANNA, FL.
RAMIREZ, GIOVANNI	WARDEN, FDC, MIAMI, FL.
WOODS, WILLIAM L	WARDEN, USP, ATLANTA, GA.
EDGE, DEREK	WARDEN, FCI, JESUP, GA.
BRAGG, M. TRAVIS	WARDEN, FCI, BENNETTSVILLE, SC.
MOSLEY, BONITA S	CORRECTIONAL PROGRAM OFFICER.
ANTONELLI, BRYAN	WARDEN, FCI, WILLIAMSBURG, SC.
ADAN, ANGEL	WARDEN, MDC, GUAYNABO, PUERTO RICO.
LOTHROP, WILLIAMS	WARDEN, FCI, PHOENIX, AZ.
BALTAZAR JR., JUAN	CORRECTIONAL PROGRAM OFFICER (REGIONAL DIRECTOR).
CARVAJAL, MICHAEL D	CORRECTIONAL PROGRAM OFFICER (ASSISTANT DIRECTOR).
MILUSNIC, LOUIS	COMPLEX WARDEN, FCC, VICTORVILLE, CA.
CIOLLIE, ANDREW	WARDEN, USP, ATWATER, CA.
YOUNG, WILLIAM	WARDEN, FCI, MENDOTA, CA.
SALAZAR, JOSIAS	WARDEN, FCI, SHERIDAN, OR.
KELLER, JEFFREY A	CORRECTIONAL PROGRAM OFFICER.
KIERNAN, SHEILA F	CORRECTIONAL PROGRAM OFFICER (SR. DEP ASST DIR), HUMAN RESOURCE MGMT. DIV.
MATEVOUSIAN, ANDRE	CORRECTIONAL PROGRAM OFFICER (SR. DEP ASST DIR), CORRECTIONAL PROGRAMS DIV.
N DIAYE, LAMINE	CORRECTNL INST ADMR (WARDEN).
PAUL, CHARLES D	CORRECTNL INST ADMR (COMPLEX WARDEN).
SCARANTINO, THOMAS J	CORRECTNL INST ADMR (COMPLEX WARDEN).
TRUE, WILLIAM PAGE	CORRECTNL INST ADMR (COMPLEX WARDEN).
VON BLANCHENSEE, BARBARA	CORRECTNL INST ADMR (COMPLEX WARDEN).
Civil Division—CIV	
DAVIS, ETHAN	PRINCIPAL DEPUTY ASSISTANT ATTORNEY GENERAL.
YAVELBERG, JAMIE ANN	DEPUTY BRANCH DIRECTOR (COMMERICIAL LITIGATION BRANCH).
MAO, ANDY	DEPUTY DIRECTOR, FRAUD SECTION.
FLENTJE, AUGUST	SPECIAL COUNSEL TO THE ASSISTANT ATTORNEY GENERAL.
LANGSAM, STEPANIE	DEPUTY SPECIAL MASTER (FUNDS ADMIN).
GRIFFITHS, JOHN R	BRANCH DIRECTOR, FEDERAL PROGRAMS.
COPPOLINO, ANTHONY J	DEPUTY BRANCH DIRECTOR.
DAVIDSON, JEANNE E	DIRECTOR, COMMERCIAL LITIGATION.
KIRSCHMAN JR., ROBERT E	DIRECTOR, COMMERCIAL LITIGATION BRANCH.
BENSON, BARRY F	DIRECTOR, AVIATION AND ADMIRALTY SECTION.
BHATTACHARYA, RUPA	DIRECTOR, TORTS BRANCH (CONSTITUTIONAL AND SPECIAL TORTS LITIGATION).
REEVES, CATHERINE	DEPUTY DIRECTOR, TORTS/CSTL—VACCINE.
GLYNN, JOHN PATRICK	DIRECTOR, TORTS BRANCH (ENVIRONMENTAL TORT LITIGATION SECTION).
EMERSON, CATHERINE V	EXECUTIVE OFFICER.
PEACHEY, WILLIAM C	DIRECTOR, OFFICE OF IMMIGRATION LITIGATION, DISTRICT COURT.
WARD, THOMAS	DEPUTY ASSISTANT ATTORNEY GENERAL (TORTS).
GRANSTON, MICHAEL D	DEPUTY ASSISTANT ATTORNEY GENERAL.
MANHARDT, KIRK	DEPUTY DIRECTOR, COMMERCIAL LITIGATION BRANCH.
DINTZER, KENNETH	DEPUTY DIRECTOR, NATIONAL COURTS.
MORELL, DAVID	DEPUTY ASSISTANT ATTORNEY GENERAL (CONSUMER PROTECTION).
HAUSKEN, GARY L	DIRECTOR, INTELLECTUAL PROPERTY.

2019 FEDERAL REGISTER—Continued

Name	Position title
BOLDEN, SCOTT	DEPUTY DIRECTOR, INTELLECTUAL PROPERTY.
GOLDBERG, RICHARD	SENIOR LEVEL TRIAL ATTORNEY, CONSUMER LITIGATION.
SHAPIRO, ELIZABETH J	DEPUTY BRANCH DIRECTOR.
HOCKEY, MARTIN	DEPUTY DIRECTOR, NATIONAL COURTS COMMERCIAL LITIGATION BRANCH.
FREEMAN, MARK	DIRECTOR, APPELLATE STAFF.
RAAB, MICHAEL	APPELLATE LITIGATION COUNSEL.
STERN, MARK B	APPELLATE LITIGATION COUNSEL.
TOUHEY, JR., JAMES G	DIRECTOR, TORTS BRANCH (FEDERAL TORT CLAIMS ACT LITIGATION).
EINERSON, ROGER	SENIOR LEVEL TRIAL ATTORNEY.
MOLINA, JR., ERNESTO	DEPUTY DIRECTOR, OFFICE OF IMMIGRATION LITIGATION, APPELLATE SECTION.
MOOPPAN, HASHIM M	DEPUTY ASSISTANT ATTORNEY GENERAL (APPELLATE).
MARTIN, DANA	DEPUTY DIRECTOR, APPELLATE BRANCH.
MCCONNELL, DAVID M	DIRECTOR, OFFICE OF IMMIGRATION LITIGATION, APPELLATE SECTION.
MCCONKEY, MILTON	DIRECTOR, BUDGET STAFF.
MCINTOSH, SCOTT R	APPELLATE COUNSEL, ADVANCED TECHNOLOGY.
BROWN, WALTER W	SENIOR LEVEL PATENT ATTORNEY.
CARNEY, CHRISTOPHER	SENIOR LEVEL TRIAL ATTORNEY.
O'MALLEY, BARBARA B	SPECIAL LITIGATION COUNSEL (AVIATION, SPACE AND ADMIRALITY).
RICKETTS, JENNIFER D	BRANCH DIRECTOR.
FURMAN, JILL	DEPUTY DIRECTOR, CONSUMER PROTECTION BRANCH.
HAAS, ALEXANDER	DIRECTOR, FEDERAL PROGRAMS.
KISOR, COLIN	SENIOR LEVEL TRIAL ATTORNEY (DEPUTY DIRECTOR).
FREEMAN, MARK	DIRECTOR, APPELLATE STAFF.
KEENER, DONALD	SENIOR LEVEL TRIAL ATTORNEY, APPELLATE.
D'ALESSIO, JR., C.S	DEPUTY DIRECTOR, CONSTITUTIONAL AND SPECIALIZED TORT LITIGATION.
QUINN, MICHAEL J	SENIOR LEVEL TRIAL ATTORNEY (CORP—FINANCIAL).
GILLIGAN, JAMES J	SPECIAL LITIGATION COUNSEL.
HARVEY, RUTH A	DIRECTOR, COMMERCIAL LITIGATION BRANCH, CORPORATE AND FINANCIAL LITIGATION.
LATOUR, MICHELLE	DEPUTY DIRECTOR, OFFICE OF IMMIGRATION LITIGATION, APPELLATE SECTION.
LIN, JEAN	SENIOR LEVEL TRIAL ATTORNEY, COMPLEX LITIGATION.
KANTER, ETHAN B	SENIOR LEVEL TRIAL ATTORNEY—NATIONAL SECURITY.
STEWART, SCOTT G	DEPUTY ASSISTANT ATTORNEY GENERAL.
Civil Rights Division—CRT	
GORE, JOHN	PRINCIPAL DEPUTY ASSISTANT ATTORNEY GENERAL.
MOOSSY, ROBERT J	DEPUTY ASSISTANT ATTORNEY GENERAL.
FELTE JR. JAMES	CHIEF, CRIMINAL SECTION.
FITZGERALD, PAIGE	PRINCIPAL DEPUTY CHIEF, CRIMINAL SECTION.
SIMONS, SHAHEENA	CHIEF, EDUCATIONAL OPPORTUNITIES SECTION.
FRIEL, GREGORY	DEPUTY ASSISTANT ATTORNEY GENERAL (APPELLATE, HOUSING & CIVIL ENFORCEMENT).
HOWE, SUSAN E	EXECUTIVE OFFICER.
TOOMEY, KATHLEEN	DIRECTOR OF OPERATIONAL MANAGEMENT.
GINSBURG, JESSICA A	COUNSEL TO THE ASSISTANT ATTORNEY GENERAL.
KENNEBREW, DELORA	CHIEF, EMPLOYMENT LITIGATION SECTION.
MAJEED, SAMEENA S	CHIEF, HOUSING AND CIVIL ENFORCEMENT SECTION.
SEWARD, JON	PRINCIPAL DEPUTY CHIEF, HOUSING AND CIVIL ENFORCEMENT SECTION.
HERREN JR., THOMAS C	CHIEF, VOTING SECTION.
WERTZ, REBECCA	PRINCIPAL DEPUTY CHIEF, VOTING SECTION.
BOND, REBECCA B	CHIEF, DISABILITY RIGHTS SECTION.
EMBREY, DIANA	CHIEF, EMPLOYMENT COUNSEL.
FORAN, SHEILA	SPECIAL LEGAL COUNSEL, DISABILITY RIGHTS SECTION.
BLUMBERG, MARK	SPECIAL LEGAL COUNSEL.
RUISANCHEZ, ALBERTO	DEPUTY SPECIAL COUNSEL FOR IMMIGRATION-RELATED UNFAIR EMPLOYMENT PRACTICES, OFFICE OF THE SPECIAL COUNSEL.
PRESTON, JUDITH L	PRINCIPAL DEPUTY CHIEF, SPECIAL LITIGATION SECTION.
RAISH, ANNE	PRINCIPAL DEPUTY CHIEF, DISABILITY RIGHTS SECTION.
WOODARD, KAREN	PRINCIPAL DEPUTY CHIEF, EMPLOYMENT LITIGATION SECTION.
ROSENBAUM, STEVEN H	CHIEF, SPECIAL LITIGATION SECTION.
LIVINGSTON, DONALD	DEPUTY ASSISTANT ATTORNEY GENERAL (DISABILITY RIGHTS).
Criminal Division—CRM	
SWARTZ, BRUCE CARLTON	DEPUTY ASSISTANT ATTORNEY GENERAL (INTERNATIONAL AFFAIRS).
AINSWORTH, PETER J	SENIOR COUNSEL, OFFICE OF OVERSEAS PROSECUTORIAL DEVELOPMENT ASSISTANCE AND TRAINING.
AMUNDSON, COREY	CHIEF, PUBLIC INTEGRITY SECTION.
CARROLL, OVIE	DIRECTOR OF THE CYBERCRIME LABORATORY.
RYBICKI, DAVID	DEPUTY ASSISTANT ATTORNEY GENERAL (HUMAN RIGHTS, ORGANIZED CRIME & GANG).
ALEXANDRE, CARL	COUNSELOR FOR TRANSNATIONAL ORGANIZED CRIME & INTL AFFAIRS.
ARY, VAUGHN	DIRECTOR, OFFICE OF INTERNATIONAL AFFAIRS.
HO-GONZALES, WILLIAM	DEPUTY DIRECTOR, OFFICE OF INTERNATIONAL AFFAIRS.

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Name	Position title
TOLEDO, RANDY	DEPUTY DIRECTOR, OFFICE OF INTERNATIONAL AFFAIRS.
CONNOR, DEBORAH L	CHIEF, MONEY LAUNDERING AND ASSET RECOVERY SECTION.
CARWILE, P	KEVIN SENIOR COUNSEL (MARITIME & COUNTERNARCOTICS).
DOWNING, RICHARD W	DEPUTY ASSISTANT ATTORNEY GENERAL.
EHRENSTAMM, FAYE	DIRECTOR, OFFICE OF OVERSEAS PROSECUTORIAL DEVELOPMET, ASSISTANCE/TRAINING.
GROCKI, STEVEN J	CHIEF, CHILD EXPLOITATION AND OBSCENITY SECTION.
HODGE, JENNIFER A.H	DIRECTOR, OFFICE OF ENFORCEMENT.
HULSER, RAYMOND N	SENIOR COUNSEL TO THE ASSISTANT ATTORNEY GENERAL.
JAFFE, DAVID	CHIEF, ORGANIZED CRIME AND GANG SECTION.
JONES, JOSEPH M	SENIOR COUNSEL FOR INTERNATIONAL DEVELOPMENT AND TRAINING.
KING, DAMON A	DEPUTY CHIEF, CHILD EXPLOITATION AND OBSCENITY SECTION.
LYNCH JR., JOHN T	CHIEF, COMPUTER CRIME, AND INTELLECTUAL PROPERTY SECTION.
MCHENRY, TERESA L	CHIEF, HUMAN RIGHTS AND SPECIAL PROSECUTIONS SECTION.
MELTON, TRACY	EXECUTIVE OFFICER.
RODRIGUEZ, MARY D	DEPUTY DIRECTOR, OFFICE OF INTERNATIONAL AFFAIRS.
ROSENBAUM, ELI M	DIRECTOR, HUMAN RIGHTS ENFORCEMENT STRATEGY AND POLICY.
STEMLER, PATTY MERKAMP	CHIEF, APPELLATE SECTION.
TIROL, ANNALOU	DEPUTY CHIEF, PUBLIC INTEGRITY SECTION.
WROBLEWSKI, JONATHAN J	DIRECTOR, OFFICE OF POLICY AND LEGISLATION.
NAZARRO, SAMUEL	SENIOR COUNSEL.
WYATT, ARTHUR G	CHIEF, NARCOTIC AND DANGEROUS DRUG SECTION.
WYDERKO, JOSEPH	DEPUTY CHIEF, APPELLATE SECTION.
CRONAN, JOHN	PRINCIPAL DEPUTY ASSISTANT ATTORNEY GENERAL/CHIEF OF STAFF.
MINER, MATTHEW	DEPUTY ASSISTANT ATTORNEY GENERAL (FRAUD AND APPELLATE).
STIGLITZ, MATTHEW	DEPUTY DIRECTOR, HUMAN RIGHTS ENFORCEMENT STRATEGY AND POLICY.
OHR, BRUCE	SENIOR COUNSEL FOR INTERNATIONAL AFFAIRS.
HARRIS, KENNETH	SENIOR JUSTICE COUNSEL.
BRYDEN, ROBERT J	DEPUTY DIRECTOR, OFFICE OF ENFORCEMENT OPERATIONS.
Environmental and Natural Resources Division—ENRD	
BRIGHTBILL, JONATHAN	PRINCIPAL DEPUTY ASSISTANT ATTORNEY GENERAL.
WILLIAMS, JEAN E	DEPUTY ASSISTANT ATTORNEY GENERAL (ENVIRONENTAL CRIMES AND WILDLIFE AND MARINE RESOURCES SECTIONS).
GELBER, BRUCE S	DEPUTY ASSISTANT ATTORNEY GENERAL.
ALEXANDER, S. CRAIG	CHIEF, INDIAN RESOURCES SECTION.
BARSKY, SETH	CHIEF, WILDLIFE AND MARINE RESOURCES.
COLLIER, ANDREW	EXECUTIVE OFFICER.
DOUGLAS, NATHANIEL	DEPUTY SECTION CHIEF, ENVIRONMENTAL ENFORCEMENT SECTION.
FERGUSON, CYNTHIA	SENIOR LITIGATION COUNSEL.
GETTE, JAMES	PRINCIPAL DEPUTY CHIEF, NATURAL RESOURCES SECTION.
GOLDFRANK, ANDREW M	CHIEF, LAND ACQUISITION SECTION.
GRANT, ERIC	DEPUTY ASSISTANT ATTORNEY GENERAL.
GRISHAW, LETITIA J	CHIEF, ENVIRONMENTAL DEFENSE SECTION.
HARRIS, DEBORAH	CHIEF, ENVIRONMENTAL CRIMES SECTION.
HOANG, ANTHONY P	SENIOR LITIGATION COUNSEL, NATURAL RESOURCES.
KILBOURNE, JAMES C	CHIEF, APPELLATE SECTION.
MAHAN, ELLEN M	PRINCIPAL DEPUTY CHIEF, ENVIRONMENTAL ENFORCEMENT SECTION.
MARIANI, THOMAS	CHIEF, ENVIRONMENTAL ENFORCEMENT SECTION.
DWORKIN, KAREN	DEPUTY CHIEF, ENVIRONMENTAL ENFORCEMENT SECTION.
MERGEN, ANDREW	PRINCIPAL DEPUTY CHIEF, APPELLATE SECTION.
HEMINGER, JUSTIN	SENIOR LITIGATION COUNSEL FOR APPELLATE MATTERS, APPELLATE SECTION.
PASSARELLI, EDWARD	DEPUTY CHIEF, ENVIRONMENTAL ENFORCEMENT.
POUX, JOSEPH	DEPUTY CHIEF, ENVIRONMENTAL CRIMES SECTION.
RUSSELL, LISA L	CHIEF, NATURAL RESOURCES SECTION.
VANDKYE, LAWRENCE	DEPUTY ASSISTANT ATTORNEY GENERAL.
HIMMELCHOCH, SARAH	SENIOR LITIGATION COUNSEL.
SINGER, FRANK	SENIOR LITIGATION COUNSEL.
STEWART, HOWARD P	SENIOR LITIGATION COUNSEL.
TENENBAUM, ALAN S	NATIONAL BANKRUPTCY COORINDATOR AND SENIOR COUNSEL.
WARDZINSKI, KAREN M	CHIEF, LAW AND POLICY SECTION.
Executive Office for Immigration Review—EOIR	
MCHENRY III, JAMES R	DIRECTOR.
REID, LAUREN	ASSISTANT DIRECTOR FOR POLICY.
SANTORO, CHRISTOPHER	DEPUTY CHIEF IMMIGRATION JUDGE.
WARD, LISA	ASSISTANT DIRECTOR FOR ADMINISTRATION.
SO, EDWARD	CHIEF INFORMATION OFFICER.
ADKINS-BLANCH, CHARLES K	VICE CHAIRMAN, BOARD OF IMMIGRATION APPEALS.
CLARK, MOLLY K	ATTORNEY EXAMINER.
COLE, PATRICIA A	ATTORNEY EXAMINER.

2019 FEDERAL REGISTER—Continued

Name	Position title
CREPPY, MICHAEL	ATTORNEY EXAMINER.
MANN, ANA	ATTORNEY EXAMINER.
GRANT, EDWARD R	ATTORNEY EXAMINER.
GREER, ANNE J	ATTORNEY EXAMINER.
GUENDELSBERGER, JOHN W	ATTORNEY EXAMINER.
KING, JEAN	GENERAL COUNSEL
LIEBOWITZ, ELLEN	ATTORNEY EXAMINER.
KELLY, EDWARD	ATTORNEY EXAMINER
MALPHRUS, GARRY D	ATTORNEY EXAMINER.
MULLANE, HUGH G	ATTORNEY EXAMINER.
O'CONNOR, BLAIR	ATTORNEY EXAMINER.
PAULEY, ROGER ANDREW	ATTORNEY EXAMINER.
STUTMAN, ROBIN M	CHIEF ADMINISTRATIVE HEARING OFFICER.
WENDTLAND, LINDA S	ATTORNEY EXAMINER.
KELLER, MARY BETH	CHIEF IMMIGRATION JUDGE.
Executive Office for Organized Crime Drug Enforcement Task Forces—OCDETF	
COHEN, ADAM	DIRECTOR, OCDETF.
PADDEN, THOMAS W	DEPUTY DIRECTOR, OCDETF.
ROTHSTEIN, JULIUS	DIRECTOR, FUSION CENTER.
Executive Office for U.S. Attorneys—EOUSA	
BELL, SUZANNE L	DEPUTY DIRECTOR (LEGAL ADVISOR).
PELLETIER, JONATHAN	CHIEF FINANCIAL OFFICER.
FLESHMAN, JAMES MARK	CHIEF INFORMATION OFFICER.
FLINN, SHAWN	CHIEF HUMAN RESOURCES OFFICER.
MACKLIN, JAMES	GENERAL COUNSEL.
SMITH, DAVID L	ATTORNEY ADVISOR (COUNSEL FOR LEGAL INITIATIVES).
WONG, NORMAN Y	DEPUTY DIRECTOR AND COUNSEL TO THE DIRECTOR.
RENO, TAMARA	COUNSEL, LEGAL PROGRAMS AND POLICY.
YANCEY, MARK	ASSOCIATE DIRECTOR, OFFICE OF LEGAL EDUCATION.
Executive Office for U.S. Trustees—EOUST	
WHITE III, CLIFFORD J	DIRECTOR.
ELLIOTT, RAMONA D	DEPUTY DIRECTOR, GENERAL COUNSEL.
HENSELY, HENREY	DEPUTY DIRECTOR MANAGEMENT.
Justice Management Division—JMD	
LOFTHUS, LEE J	ASSISTANT ATTORNEY GENERAL FOR ADMINISTRATION.
ALLEN, MICHAEL H	DEPUTY ASSISTANT ATTORNEY GENERAL FOR POLICY, MANAGEMENT AND PLANNING.
LAURIA JOLENE A	DEPUTY ASSISTANT ATTORNEY GENERAL/CONTROLLER.
KLIMAVICZ, JOSEPH	DEPUTY ASSISTANT ATTORNEY GENERAL FOR INFORMATION TECHNOLOGY MANAGEMENT AND CHIEF INFORMATION OFFICER.
WILKINSON, ROBERT M	DEPUTY ASSISTANT ATTORNEY GENERAL FOR HUMAN RESOURCES AND ADMINISTRATION.
LAMARY, MARY	DIRECTOR, HUMAN RESOURCES.
GARY, ARTHUR	GENERAL COUNSEL.
SHAW, CYNTHIA	DIRECTOR, DEPARTMENTAL ETHICS OFFICE.
ALVAREZ, CHRISTOPHER C	DIRECTOR, FINANCE STAFF.
DUNLAP, JAMES L	DIRECTOR, SECURITY AND EMERGENCY PLANNING STAFF.
SNELL, ROBERT	DIRECTOR, FACILITIES AND ADMINISTRATIVE SERVICES STAFF.
FELDT, DENNIS G	DIRECTOR, LIBRARY STAFF.
NACCARATO, TOM	DIRECTOR, PROCUREMENT SERVICES STAFF.
DAUPHIN, DENNIS E	DIRECTOR, DEBT COLLECTION MANAGEMENT STAFF.
PULLEN, JEFFREY	SENIOR ADVISOR FOR FINANCIAL MANAGEMENT INFORMATION TECHNOLOGY.
FUNSTON, ROBIN S	DIRECTOR, STRATEGIC PLANNING AND PERFORMANCE.
ATTUCKS, MARK	DEPUTY DIRECTOR, BUDGET STAFF, OPERATIONS AND FUNDS CONTROL.
KLEPPINGER, ERIC D	DEPUTY DIRECTOR, BUDGET STAFF, PROGRAMS AND PERFORMANCE.
ROGERS, MELINDA	DEPUTY CHIEF INFORMATION OFFICER.
BEWTRA, ANEET K	CHIEF TECHNOLOGY OFFICER.
TOSCANO JR., RICHARD A	DIRECTOR, EQUAL EMPLOYMENT OPPORTUNITY STAFF.
COOK, TERENCE L	SENIOR ADVISOR.
ROPER, MATTHEW	DEPUTY DIRECTOR (AUDITING), FINANCE STAFF.
CONNELLY, ROBERT L	DIRECTOR, OSDBU.
SMITH, RICHARD	CONSOLIDATED DEBT COLLECTION SYSTEM.
MITCHELL, KRYSTLE	CHIEF LEARNING OFFICER.
WASHINGTON JR., RUSSELL	SR. LAW ENFORCEMENT ADVISOR TO THE CIO.
WARD, NICKOLOUS	DIRECTOR, CYBERSECURITY SERVICES STAFF/CISO.
SMITH, LINDA	DIRECTOR, BUDGET STAFF.

2019 FEDERAL REGISTER—Continued

Name	Position title
MCKEOWN, DAVID	DIRECTOR, SERVICE DELIVERY STAFF.
SJOBERG-RADWAY, CYNTHIA	DIRCTOR, POLICY AND PLANNING STAFF (OCIO).
National Security Division—NSD	
BURNS, DAVID	PRINCIPAL DEPUTY ASSISTANT ATTORNEY GENERAL.
HICKEY, ADAM	DEPUTY ASSISTANT ATTORNEY GENERAL.
ANDREWS, KELLI	CHIEF OF STAFF AND COUNSELOR.
WIEGMANN, JOHN B	DEPUTY ASSISTANT ATTORNEY GENERAL, OFFICE OF LAW AND POLICY.
TOSCAS, GEORGE Z	DEPUTY ASSISTANT ATTORNEY GENERAL, COUNTERESPIONAGE-COUNTERTERRORISM.
RAMELLA SMITH, JENNIFER	CHIEF, COUNTERTERRORISM SECTION.
JAYARAM, SANCHITHA	CHIEF, FOREIGN INVESTMENT REVIEW STAFF.
DUNNE, STEVEN M	CHIEF, APPELLATE UNIT.
RALEY, MAUREEN	SENIOR ADVISOR, TECHNOLOGY AND INVESTMENT RISK.
KEEGAN, MICHAEL	CHIEF, COUNTERTERRORISM SECTION.
BRATT, JAY	CHIEF, COUNTERINTELLIGENCE, EXPORT CONTROL AND ECONOMIC ESPIONAGE.
KENNEDY, J. LIONEL	SPECIAL COUNSEL FOR NATIONAL SECURITY.
O'CONNOR, KEVIN	CHIEF, OVERSIGHT SECTION.
SANZ-REXACH, GABRIEL	CHIEF, OPERATIONS SECTION
HARDEE, CHRISTOPHER	CHIEF, POLICY-OFFICE OF LAW AND POLICY.
PALMER, DAVID	SENIOR COUNSELOR TO THE ASSISTANT ATTORNEY GENERAL.
Office of Community Oriented Policing Services—COPS	
KEITH, PHILLIP	DIRECTOR.
BROWN-CUTLAR, SHANETTA	SENIOR COUNSEL TO THE DIRECTOR.
Office of Justice Programs—OJP	
SULLIVAN, KATHARINE	PRINCIPAL DEPUTY ASSISTANT ATTORNEY GENERAL.
HENNEBERG, MAUREEN A	DEPUTY ASSISTANT ATTORNEY GENERAL, OPERATIONS MANAGEMENT.
COSTIGAN, MICHAEL	CHIEF OF STAFF.
GARRY, EILEEN M	DIRECTOR FOR SPECIAL PROJECTS.
TRAUTMAN, TRACEY	DEPUTY DIRECTOR FOR PROGRAMS, BUREAU OF JUSTICE ASSISTANCE.
SPIVAK, HOWARD	PRINCIPAL DEPUTY DIRECTOR, NATIONAL INSTITUTE OF JUSTICE.
MARTIN, RALPH	DIRECTOR, OFFICE OF AUDIT, ASSESSMENT, AND MANAGEMENT.
MERKLE, PHILIP	DIRECTOR, OFFICE OF ADMINISTRATION.
MADAN, RAFAEL A	GENERAL COUNSEL.
MAHONEY, KRISTEN	DEPUTY DIRECTOR FOR POLICY.
MCGRATH, BRIAN	CHIEF INFORMATION OFFICER.
BENDA, BONNIE LEIGH	CHIEF FINANCIAL OFFICER.
DUMMERUTH, MATTHEW	SENIOR COUNSELOR.
BARNETT, GARY	SENIOR COUNSELOR.
TOESING, BRADY	SENIOR COUNSELOR.
BECK, ALLEN J	SENIOR STATISTICIAN.
DARDEN, SILAS	DIRECTOR, OFFICE OF COMMUNICATIONS.
JONES, CHYRL	DEPUTY ADMINISTRATOR.
Office of Legal Counsel—OLC	
GANNON, CURTIS	PRINCIPAL DEPUTY ASSISTANT ATTORNEY GENERAL OF LEGAL COUNSEL.
KOFFSKY, DANIEL L	DEPUTY ASSISTANT ATTORNEY GENERAL.
WHITAKER, HENRY	DEPUTY ASSISTANT ATTORNEY GENERAL.
HARDY, LIAM	DEPUTY ASSISTANT ATTORNEY GENERAL.
MASCOTT, JENNIFER	DEPUTY ASSISTANT ATTORNEY GENERAL.
COLBORN, PAUL P	SPECIAL COUNSEL.
HART, ROSEMARY A	SPECIAL COUNSEL.
SINGDAHLSEN, JEFFREY P	SENIOR COUNSEL.
Office of Legal Policy—OLP	
JONES, KEVIN ROBERT	DEPUTY ASSISTANT ATTORNEY GENERAL.
THIEMANN, ROBYN L	DEPUTY ASSISTANT ATTORNEY GENERAL.
DHILLON, UTTAM A	SENIOR COUNSELOR.
KARP, DAVID J	SENIOR COUNSEL.
CRYTZER, KATIE	SENIOR COUNSEL.
CHAMPOUX, MARK	PRINCIPAL DEPUTY ASSISTANT ATTORNEY GENERAL.
Office of Legislative Affairs—OLA	
HANKEY, MARY BLANCHE	CHIEF OF STAFF AND COUNSELOR.
NOLAN, CHERI	SENIOR ADVISOR FOR LAW ENFORCEMENT RELATIONS.
ESCALONA, PRIM	PRINCIPAL DEPUTY ASSISTANT ATTORNEY GENERAL.

2019 FEDERAL REGISTER—Continued

Name	Position title
LASSETER, DAVID	DEPUTY ASSISTANT ATTORNEY GENERAL.
Office of Professional Responsibility—OPR	
ASHTON, ROBIN	SENIOR COUNSELOR.
RAGSDALE, JEFFREY	DEPUTY COUNSEL ON PROFESSIONAL RESPONSIBILITY.
BIRNEY, WILLIAM	SENIOR ASSOCIATE COUNSEL.
MCCARTY, MARGARET	SENIOR ASSOCIATE COUNSEL.
Office of Public Affairs—PAO	
KUPEC, KERRI	DIRECTOR.
LLOYD, MATTHEW	PRINCIPAL DEPUTY DIRECTOR.
Office of Tribal Justice—OTJ	
TOULOU, TRACY S	DIRECTOR, OFFICE OF TRIBAL JUSTICE.
Office on Violence Against Women (OVW)	
ROGERS, LAURA	PRINCIPAL DEPUTY DIRECTOR.
Professional Responsibility Advisory Office—PRAO	
LUDWIG, STACY	DIRECTOR.
Tax Division—TAX	
HUBBERT, DAVID A	DEPUTY ASSISTANT ATTORNEY GENERAL.
WU, JOSHUA	DEPUTY ASSISTANT ATTORNEY GENERAL.
BRUFFY, ROBERT	EXECUTIVE OFFICER.
BALLWEG, MITCHELL	COUNSELOR TO THE DEPUTY ASSISTANT ATTORNEY GENERAL FOR STRATEGIC TAX ENFORCEMENT.
WSZALEK, LARRY	CHIEF, CRIMINAL ENFORCEMENT SECTION, WESTERN REGION.
DALY, MARK	SENIOR LEVEL TRIAL ATTORNEY.
DAVIS, NANETTE	SENIOR LEVEL TRIAL ATTORNEY.
DONOHUE, DENNIS M	SENIOR LITIGATION COUNSEL.
PINCUS, DAVID	CHIEF, COURT OF FEDERAL CLAIMS SECTION.
GOLDBERG, STUART	SENIOR COUNSELOR TO THE ASSISTANT ATTORNEY GENERAL.
HAGLEY, JUDITH	SENIOR LEVEL TRIAL ATTORNEY.
IHLO, JENNIFER	SENIOR LEVEL TRIAL ATTORNEY.
CLARKE, RUSSELL SCOTT	CHIEF, CIVIL TRIAL SECTION, CENTRAL REGION.
JOHNSON, CORY	SENIOR LEVEL TRIAL ATTORNEY.
FRATTARELLI, ANGELO	CHIEF, CIVIL TRIAL SECTION, SOUTHERN REGION.
LARSON, KARI	SENIOR LEVEL TRIAL ATTORNEY.
LINDQUIST III, JOHN A	SENIOR LEVEL TRIAL ATTORNEY.
KATINSKY, DAVID	CHIEF, CIVIL TRIAL SECTION, NORHTERN REGION.
MELAND, DEBORAH	CHIEF, CIVIL TRIAL SECTION EASTERN REGION.
FRATTARELLI, ANGELO	CHIEF, CIVIL TRIAL SECTION, SOUTHERN REGION.
REID, ANN C.	CHIEF, OFFICE OF REVIEW.
PAGUNI, ROSEMARY E	CHIEF, CRIMINAL ENFORCEMENT SECTION, NORTHERN REGION.
ROTHENBERG, GILBERT S	CHIEF, APPELLATE SECTION.
CLARK, THOMAS J	DEPUTY CHIEF, APPELLATE SECTION.
LYONS, ROBERT	CHIEF, CRIMINAL APPEALS AND TAX ENFORCEMENT POLICY SECTION.
SAWYER, THOMAS	SENIOR LEVEL TRIAL ATTORNEY.
SERGI, JOSEPH A	SENIOR LEVEL TRIAL ATTORNEY.
SHATZ, EILEEN M	SPECIAL LITIGATION COUNSEL.
SMITH, COREY J	SENIOR LEVEL TRIAL ATTORNEY.
STEHLIK, NOREENE C	SENIOR LEVEL TRIAL ATTORNEY.
SULLIVAN, JOHN	SENIOR LEVEL TRIAL ATTORNEY.
WEAVER, JAMES E	SENIOR LEVEL TRIAL ATTORNEY.
WARD, RICHARD	CHIEF, CIVIL TRIAL SECTION WESTERN REGION.
ZUCKERMAN, RICHARD	DEPUTY ASSISTANT ATTORNEY GENERAL.
GREAVES, TRAVIS	DEPUTY ASSISTANT ATTORNEY GENERAL.
U.S. Marshals Service—USMS	
AUERBACH, GERALD	GENERAL COUNSEL.
CAMPBELL KREIGER, DIANNI	ASSISTANT DIRECTOR, HUMAN RESOURCES.
BROWN, SHANNON B	ASSISTANT DIRECTOR, JPATS.
MOHAN, KATHERINE T	ASSOCIATE DIRECTOR FOR ADMINISTRATION.
DRISCOLL, DERRICK	DEPUTY DIRECTOR.
MATHIAS, KARL	ASSISTANT DIRECTOR FOR INFORMATION TECHNOLOGY.

2019 FEDERAL REGISTER—Continued

Name	Position title
BOLEN, JOHN	ASSISTANT DIRECTOR, OFFICE OF INSPECTION.
VIRTUE, TIMOTHY	ASSISTANT DIRECTOR, ASSET FORFEITURE.
HACKMASTER, NELSON	ASSOCIATE DIRECTOR FOR OPERATIONS.
DICKINSON, LISA	ATTORNEY ADVISOR.
O'BRIEN-ROGAN, CAROLE	PROCUREMENT EXECUTIVE, FINANCIAL SERVICES.
O'BRIEN, HOLLEY	CHIEF, FINANCIAL OFFICER, FINANCIAL SERVICES.
O'HEARN, DONALD	ASSISTANT DIRECTOR FOR WITNESS SECURITY.
TYLER, JEFFREY	ASSISTANT DIRECTOR, INVESTIGATIVE OPERATIONS.
HICKMAN, KATE	ASSISTANT DIRECTOR, MANAGEMENT SUPPORT.
WHITE, DARRELL	ASSISTANT DIRECTOR, JUDICIAL SECURITY.
ROBINSON, ROBERTO	ASSISTANT DIRECTOR, TACTICAL OPERATIONS.
BRUNER, JARROD	SUPERVISORY IT PROGRAM MANAGER.
Community Relations Service—CRS	
RATIFF, GERRI	DEPUTY DIRECTOR.
Rule of Law Office—ROL	
MOTT, JOSEPH	JUSTICE ATTACHE, AFGHANISTAN.

[FR Doc. 2019–23381 Filed 10–24–19; 8:45 am]

BILLING CODE 4410–CH–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Operations Mining Under a Body of Water

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Mine Safety and Health Administration (MSHA) sponsored information collection request (ICR) titled, ''Operations Mining Under a Body of Water,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before November 25, 2019.

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=201906-1219-001* (this link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–MSHA, 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: Frederick Licari by telephone at 202–693–8073, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Operations Mining Under a Body of Water information collection. Section 103(h) of the Federal Mine Safety and Health Act of 1977 (Mine Act), 30 U.S.C. 813(h), authorizes MSHA to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811, authorizes the Secretary of Labor (Secretary) to develop, promulgate, and revise as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal and metal and nonmetal mines. Title 30 CFR Sections 75.1716, 75.1716–1 and 75.1716–3 require operators of underground coal mines to provide MSHA notification before mining under bodies of water and to obtain a permit to mine under a body of water if, in the judgment of the Secretary, it is sufficiently large to constitute a hazard to miners. The regulation is necessary to prevent the inundation of underground coal mines with water that has the potential of drowning miners. The coal mine operator submits an application for the permit to the District Manager in whose district the mine is located. Applications contain the name and address of the mine; projected mining and ground support plans; a mine map showing the location of the river, stream, lake or other body of water and its relation to the location of all working places; and a profile map showing the type of strata and the distance in elevation between the coal bed and the water involved. MSHA has provided an exemption from notification and permit application for mine operators where the projected mining is under any water reservoir constructed by a Federal agency as of December 30, 1969, and where the operator is required by such agency to operate in a manner that adequately protects the safety of miners. The exemption for such mining is addressed by 30 CFR Sections 75.1716 and 75.1717. MSHA also encourages a mine operator to provide more information in an application. When the operator files an application for a permit, in addition to the information required under 30 CFR Section 75.1716–3, operators are also encouraged to include a map of the active areas of the

mine under the body of water showing the following: Bottom of coal elevations (minimum 10-ft contour intervals); the limits of the body of water and the estimated quantity of water in the pool; the limits of the proposed ''safety zone'' within which precautions will be taken; overburden thickness (depth of cover) contours; corehole locations; and known faults, lineaments, and other geologic features. If the body of water is contained within an overlying mine, then MSHA recommends a map of the overlying mine showing bottom of coal elevations (minimum 10-ft contour intervals), when available, corehole locations, the limits of the body of water with the estimated quantity of water in the pool, and interburden to active mine below be provided. Operators are also encouraged to submit the methods that were used to estimate the quantity of water in the pool, borehole logs, including geotechnical information (RQD, fracture logs, etc.) if available; rock mechanics data on the overburden, interburden, mine roof, and mine floor, if available; mining height of the seam being mined, pillar and floor stability analyses for the active mine, whether second mining is planned, whether mining will be conducted down-dip or up-dip, where water will flow to in the active mine if encountered, pumping capabilities for dewatering, a comprehensive evacuation plan for the miners, and a statement of what in-mine conditions would trigger the implementation of the evacuation plan, and training that will be provided to the miners regarding the potential hazards.

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 the OMB under the PRA approves it 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 1219–0020.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on October 31, 2019. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on August 21, 2019 (84 FR 43621).

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 1219–0020. 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 appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–MSHA.

Title of Collection: Operations Mining Under a Body of Water.

OMB Control Number: 1219–0020.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 77.

Total Estimated Number of Responses: 77.

Total Estimated Annual Time Burden: 424 hours.

Total Estimated Annual Other Costs Burden: $1,040.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: October 17, 2019.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2019–23299 Filed 10–24–19; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Post Enrollment Data Collection for Job Corps Participants

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting the Employment Training Administration (ETA) sponsored information collection request (ICR) revision titled, ''Post Enrollment Data Collection for Job Corps Participants,'' 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 November 25, 2019.

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=201909-1205-003* (this link will only become active on the day following publication of this notice) or by contacting Frederick Licari by telephone at 202–693–8073, 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 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: Frederick Licari by telephone at 202–693–8073, 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 Post Enrollment Data Collection for Job Corps Participants information collection. These data will be used to assess the effectiveness of the Job Corps program in meeting its objectives under the Workforce Innovation Opportunity Act (WIOA). The Office of Job Corps will incorporate these data into the Outcome Measurement System to evaluate the post-center outcomes of graduates and former enrollees. Job Corps will use the information about student outcomes and customer feedback about satisfaction with specific services to develop or refine policies to improve the delivery of educational and job training services to at-risk youth. The Workforce Innovation Opportunity Act (WIOA), Section 116(b)(2)(A)(i) and Section 159(c)(4) authorizes this information collection.

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 the OMB, under the PRA, approves it 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 1205–0426. The current approval is scheduled to expire on October 31, 2019 however, the DOL notes that existing information collection requirements submitted to the OMB will 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 July 03, 2019 (84 FR 31917).

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 1205–0426.

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 appropriate 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: Post Enrollment Data Collection for Job Corps Participants.

OMB Control Number: 1205–0426.

Affected Public: Individuals or Households; Private Sector—Not-for-profit institutions, businesses, or other for-profits.

Total Estimated Number of Respondents: 49,200.

Total Estimated Number of Responses: 93,400.

Total Estimated Annual Time Burden: 21,700 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: October 18, 2019.

Frederick Licari,

Departmental Clearance Officer.

[FR Doc. 2019–23298 Filed 10–24–19; 8:45 am]

BILLING CODE 4510–FT–P

DEPARTMENT OF LABOR

Office of the Secretary

[DOL Docket No. DOL–2019–0007]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, Department of Labor.

ACTION: Notice of a new system of records.

SUMMARY: The Office of the Secretary of Labor at the Department of Labor (DOL) proposes to add a new system of records to its inventory of records systems subject to the Privacy Act of 1974, as amended. This action is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of records maintained by the agency.

DATES: This System of Records Notice (SORN) is effective upon its publication in today's **Federal Register** with the exception of the routine uses. The new routine uses will not be effective until November 25, 2019 pending public comment. Comments on the new routine uses or other aspects of the SORN must be submitted on or before November 25, 2019.

ADDRESSES: Submit your comments by one of the following methods:

Electronic Comments: Comments may be sent via *http://www.regulations.gov,* a Federal E-Government website that allows the public to find, review, and submit comments on documents that agencies have published in the **Federal Register** and that are open for comment.

Mail: Address written submissions (including disk and CD–ROM submissions) to Hong Kim, Office of the Assistant Secretary for Policy, U.S. Department of Labor, 200 Constitution Avenue NW, Suite 2218, Washington, DC 20210, (202) 693–5959 (this is not a toll-free number).

Instructions: Please submit only one copy of your comments by only one method. All submissions must include the agency's name and the Docket Number DOL–2019–0007. Please be advised that comments received will become a matter of public record and will be posted without change to *http://www.regulations.gov,* including any personal information provided. Comments that are mailed must be received by the date indicated for consideration.

Docket: For access to the docket to read background documents or comments, go to the Federal e-Rulemaking Portal at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Hong Kim, Office of the Assistant Secretary for Policy, U.S. Department of Labor, 200 Constitution Avenue NW, Suite 2218, Washington, DC 20210, (202) 693–5959 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department of Labor has established a system of records pursuant to the Privacy Act of 1974 (5 U.S.C. 552a(e)(4)), hereinafter referred to as the Privacy Act. The Office of the Secretary of Labor notices for systems of records subject to the Privacy Act, have been published in the **Federal Register** and are available from the address above. The Department hereby publishes notice of one new system of records.

The Federal Docket Management System (FDMS) allows the public to search, view, download, and comment on all Federal agency rulemaking documents in one central online system. The FDMS serves as a central electronic

repository for all Federal rulemaking dockets, which include **Federal Register** notices, supporting materials such as scientific or economic analyses, and public comments, as well as non-rulemaking dockets. The FDMS is a system used by all Federal agencies that conduct rulemakings. Each agency is responsible for managing its own docket and rulemaking documents.

The proposed new system is entitled DOL/CENTRAL–8, Department of Labor Federal Docket Management System (DOLFDMS). This system contains records submitted via the FDMS. The proposed new system, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted to the Office of Management and Budget, the Committee on Oversight and Government Reform of the House of Representatives, and the Committee on Homeland Security and Governmental Affairs of the Senate pursuant to OMB Circular A–108.

SYSTEM NAME AND NUMBER:

Department of Labor Federal Docket Management System (DOLFDMS), DOL/CENTRAL–8.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Primary location: Offices in various components within the U.S. Department of Labor, at the Frances Perkins Building, 200 Constitution Avenue NW, Washington, DC 20210, or other Department offices. Additionally, pursuant to the Department of Labor's Flexiplace Programs (also known as ''telework'' pursuant to the Telework Enhancement Act), copies of records may be temporarily located at alternative worksites, including employees' homes or at geographically convenient satellite offices for part of the workweek. All appropriate safeguards will be taken at these sites.

Third-party service provider: General Services Administration, 1800 F Street NW, Washington, DC 20405.

SYSTEM MANAGER(S):

Hong Kim, Office of the Assistant Secretary for Policy, Office of Regulatory and Programmatic Policy, U.S. Department of Labor, 200 Constitution Avenue NW, Suite 2218, Washington, DC 20210, (202) 693–5959 (this is not a toll-free number).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Administrative Procedure Act, 5 U.S.C § 551 *et seq.* (1946); The Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* (1995).

PURPOSE(S) OF THE SYSTEM:

The purpose of this system of records is to permit the Department of Labor (DOL) to identify individuals who have submitted comments in response to DOL and component sub-agencies rulemaking documents or notices so that communications or other actions, as appropriate and necessary, can be effected, such as a need to seek clarification of the comment, providing a direct response if warranted, and for such other needs as may be associated with the rulemaking or notice process. Additional purposes include providing the public with a central online location to search, view, download and comment on Federal rulemaking documents.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any individual who provides personal information when submitting a public comment and/or supporting materials in response to a Department of Labor, or its sub-agencies, rulemaking document or notice.

CATEGORIES OF RECORDS IN THE SYSTEM:

Agency rulemaking materials including, but not limited to, **Federal Register** publications, supporting rulemaking documentation, scientific and financial studies and public comments. Information submitted by public comment may include full name, postal address, email address, phone and fax number, name of the organization the individual represents, name of any individual serving as a representative for the individual submitting the comment, and the comments, as well as other supporting documentation, furnished by the individual.

RECORD SOURCE CATEGORIES:

Records deriving from individuals commenting on Federal rulemaking activities.

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 to authorized entities, as is determined to be relevant and necessary, outside DOL as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

CONGRESSIONAL INQUIRIES DISCLOSURE ROUTINE USE:

The following Universal Routine Use for DOL Privacy Act Systems applies: Disclosure from a system of records maintained by a DOL Agency may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

DISCLOSURE TO THE DEPARTMENT OF JUSTICE FOR LITIGATION ROUTINE USE:

The following Universal Routine Use for DOL Privacy Act Systems applies: To the Department of Justice when: (a) DOL or any component thereof; or (b) any employee of DOL in his or her official capacity; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, DOL determines that the records are both relevant and necessary to the litigation, and the use of such records by the Department of Justice is for a purpose that is compatible with the purpose for which DOL collected the records.

DISCLOSURE OF INFORMATION TO THE NATIONAL ARCHIVES AND RECORDS ADMINISTRATION ROUTINE USE:

The following Universal Routine Use for DOL Privacy Act Systems applies: A record from a system of records maintained by a DOL Agency may be disclosed as a routine use to the National Archives and Records Administration for the purpose of records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

PRIVACY ACT ROUTINE USES REQUIRED TO RESPOND TO A BREACH:

(1) To appropriate agencies, entities, and persons when (1) DOL suspects or has confirmed that there has been a breach of the system of records, (2) DOL has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOL (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 DOL efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(2) To another Federal agency or Federal entity, when DOL 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.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Paper file folders and electronic storage media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The system has the ability to retrieve records by numerous data elements and key word searches, including name, agency, dates, subject, docket type, docket sub-type, agency docket ID, docket title, docket category, document type, CFR Part, date received, **Federal Register** publication date, and other information retrievable with full-text searching capability.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Comments on rulemaking are permanent; retired to a Federal Records Center when superseded; and transferred to the National Archives when 30 years old. Comments on notices are disposed of after one (1) year.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are maintained in a secure, password protected electronic system that utilizes security hardware and software to include: Multiple firewalls, active intruder detection, and role-based access controls. Paper records will be maintained in a controlled facility where physical entry is restricted by the use of locks, guards, or administrative procedures. Access to records is limited to those officials who require the records to perform their official duties consistent with the purpose for which the information was collected. All personnel whose official duties require access to the information are trained in the proper safeguarding and use of the information.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address a written request to the Office of the Assistant Secretary for Policy, Office of Regulatory and Programmatic Policy, 200 Constitution Avenue NW, Washington, DC 20210.

Signed, written requests should contain full name, address, and telephone number. As appropriate, requests may be referred to the DOL Agency responsible for the rulemaking or notice for processing.

Note: FDMS permits a member of the public to download any of the public comments received. If an individual has voluntarily furnished his or her name when submitting the comment, the individual, as well as the public, can view and download the comment by searching on the name of the individual. If the comment is submitted electronically using the FDMS system, the viewed comment will not include the name of the submitter or any other identifying information about the individual except that which the submitter has opted to include as part of his or her general comments. However, a comment submitted in writing that has been scanned and uploaded into the FDMS system will display the submitter's identifying information that has been included as part of the written correspondence.

CONTESTING RECORD PROCEDURES:

A petition for amendment should be mailed to the System Manager, and should include contact information for the requester. Requests for correction or amendment must identify the record to be changed and the corrective action sought.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Department of Labor, Office of the Assistant Secretary for Policy, Office of Regulatory and Programmatic Policy, 200 Constitution Avenue NW, Washington, DC 20210. Requests should contain full name, address, and telephone number.

Note: FDMS permits an individual, as well as a member of the public, to search the public comments received by the name of the individual submitting the comment. Unless the individual submits the comment anonymously, a name search will result in the comment being displayed for view. If the comment is submitted electronically using the FDMS system, the viewed comment will not include the name of the submitter or any other identifying information about the individual except that which the submitter has opted to include as part of his or her general comments. However, a comment submitted in writing that has been scanned and uploaded into the FDMS system will display the submitter's identifying information that has been included as part of the written correspondence.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Dated: October 16, 2019.

Bryan Slater,

Assistant Secretary for Administration & Management.

[FR Doc. 2019–22922 Filed 10–24–19; 8:45 am]

BILLING CODE 4510–04–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Agency Information Collection Activities: Announcement of the Office of Management and Budget (OMB) Control Numbers Under the Paperwork Reduction Act

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice; announcement of the Office of Management and Budget's (OMB) approval of information collection requirements.

SUMMARY: Comporting with Executive Order 13563, ''Improving Regulations and Regulatory Review,'' and consistent with Executive Order 13777, ''Enforcing the Regulatory Reform Agenda,'' OSHA removed or revised outdated, duplicative, unnecessary, and inconsistent requirements in safety and health standards. Standards Improvement Project—Phase IV (SIP–IV) was published May 14, 2019 (84 FR 21416, Docket Number OSHA–2012–0007). This final rule reduces regulatory burden while maintaining or enhancing worker safety and health, and improving privacy protections.

The Occupational Safety and Health Administration announces an OMB extension of approval for a number of information collection requirements found in the final rule. OSHA sought approval of these requirements under the Paperwork Reduction Act of 1995 (PRA), and, as required by that Act, is announcing the approval numbers and expiration dates for these requirements.

DATES: This notice is effective October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION: The purposes of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* include enhancing the quality and utility of information the Federal government requires and minimizing the paperwork and reporting burden on affected entities. The public is not required to respond to a collection of information unless it displays a currently valid OMB control number (44 U.S.C. 3507). Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if there is not a current valid OMB control number (44 U.S.C. 3512).

The Department submitted a series of Information Collection Requests (ICRs) to revise the collections in accordance with the SIP–IV Final Rule, as required by the PRA. See 44 U.S.C. 3507(d). Some of the revisions resulted in changes to the existing burden hour and/or cost estimates. Other revisions were less significant and did not change the ICR burden hour and cost estimates.

SIP–IV modified twenty-five Information Collections currently approved by the Office of Management and Budget (OMB) under the PRA. They are listed in the table along with the OMB Control Number and their current expiration date. In accordance with 5 CFR 1320.5(b), an agency cannot conduct, sponsor, or require a response to a collection of information unless the collection displays a valid OMB control number and the agency informs respondents that they need not respond to the collection of information.

Title of the information collection request	OMB Control No.	Expiration date
1,2-Dibromo-3-Choropropane (DBCP) Standard (29 CFR 1910.1044)	1218–0101	08/31/2022
1,3-Butadiene Standard (29 CFR 1910.1051)	1218–0170	01/31/2020
4,4′-Methylenedianiline (MDA) in Construction (29 CFR 1926.60)	1218–0183	07/31/2022
4,4′-Methylenedianiline (MDA) for General Industry (29 CFR 1910.1050)	1218–0184	01/31/2020
Acrylonitrile (29 CFR 1910.1045)	1218–0126	07/31/2022
Asbestos in Construction Standard (29 CFR 1926.1101)	1218–0134	10/31/2021
Asbestos in General Industry (29 CFR 1910.1001)	1218–0133	04/30/2020
Asbestos in Shipyards (29 CFR 1915.1001)	1218–0195	04/30/2020
Benzene (29 CFR 1910.1028)	1218–0129	01/31/2020
Bloodborne Pathogens Standard (29 CFR 1910.1030)	1218–0180	08/31/2021
Cadmium in Construction (29 CFR 1926.1127)	1218–0186	01/31/2020
Cadmium in General Industry (29 CFR 1910.1027)	1218–0185	01/31/2020
Coke Oven Emissions (29 CFR 1910.1029)	1218–0128	07/31/2022
Construction Standards on Posting Emergency Telephone Numbers and Floor Load Limits (29 CFR 1926.50 and 29 CFR 1926.250)	1218–0093	07/31/2022
Cotton Dust (29 CFR 1910.1043)	1218–0061	08/31/2021
Ethylene Oxide (EtO) Standard (29 CFR 1910.1047)	1218–0108	09/30/2020
Formaldehyde Standard (29 CFR 1910.1048)	1218–0145	04/30/2020
Hazardous Waste Operations and Emergency Response for General Industry (29 CFR 1910.120) and Construction (29 CFR 1926.65)	1218–0202	01/31/2020
Hexavalent Chromium Standards for General Industry (29 CFR 1910.1026)	1218–0252	01/31/2020
Inorganic Arsenic Standard (29 CFR 1910.1018)	1218–0104	07/31/2022
Lead in Construction Standard (29 CFR 1926.62)	1218–0189	07/31/2022
Lead in General Industry Standard (29 CFR 1910.1025)	1218–0092	01/31/2020
Methylene Chloride (29 CFR 1910.1052)	1218–0179	08/31/2021
Respirable Crystalline Silica Standards for General Industry, Shipyard Employment and Marine Terminals (29 CFR 1910.1053) and Construction (29 CFR 1926.1153)	1218–0266	01/31/2020
Vinyl Chloride Standard (29 CFR 1910.1017)	1218–0010	08/31/2021

Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on October 18, 2019.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2019–23295 Filed 10–24–19; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Agency Information Collection Activities: Announcement of the Office of Management and Budget (OMB) Control Numbers Under the Paperwork Reduction Act

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice; announcement of the Office of Management and Budget's (OMB) approval of information collection requirements.

SUMMARY: The Occupational Safety and Health Administration announces that OMB extended approval for information collection requirements found in OSHA's standards and regulations outlined in this notice. OSHA sought approval of these requirements under the Paperwork Reduction Act of 1995 (PRA), and, as required by that Act, is announcing the approval numbers and expiration dates for these requirements and regulations.

DATES: This notice is applicable October 25, 2019.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION: In a series of **Federal Register** notices, the various information collection (paperwork) requirements in its safety and health standards pertaining to general industry, construction, and shipyard employment, and regulations pertaining to On-Site Consultation Agreements, Variances, OSHA Strategic Partnership Program for Workers' Safety and Health, and National Safety Stand-Down to Prevent Falls in Construction (*i.e.,* 29 CFR parts 1904, 1905, 1908, 1910, 1915, 1917, 1918, and 1926). In these **Federal Register** announcements, the agency provided 60-day comment periods for the public to respond to OSHA's burden hour and cost estimates.

In accordance with the PRA (44 U.S.C. 3501–3520), OMB approved these information collection requirements. The table provides the

following information for each of these requirements approved by OMB: the title of the **Federal Register** notice; the **Federal Register** reference (date, volume, and leading page); OMB's Control Number; and the new expiration date.

In accordance with 5 CFR 1320.5(b), an agency cannot conduct, sponsor, or require a response to a collection of information unless the collection displays a valid OMB control number and the agency informs respondents that they need not respond to the collection of information.

Title of the information collection request	Date of **Federal Register** Publication, **Federal Register** Reference, and OSHA Docket No.	OMB Control No.	Expiration date
13 Carcinogens Standard (29 CFR 1910.1003, 1915.1003, and 1926.1103)	June 19, 2018, 83 FR 28451, Docket No. OSHA–2011–0860.	1218–0085	03/31/2022
Blasting Operations and the Use of Explosives (29 CFR part 1926, subpart U).	April 19, 2018, 83 FR 17447, Docket No. OSHA–2011–0747.	1218–0217	02/28/2022
Bloodborne Pathogens Standard (29 CFR 1910.1030)	April 18, 2018, 83 FR 17194, Docket No. OSHA–2010–0047.	1218–0180	08/31/2021
Commercial Diving Operations Standard (29 CFR part 1910, subpart T)	March 21, 2019, 84 FR 10553, Docket No. OSHA–2011–0008.	1218–0069	07/31/2022
Electrical Standards for Construction (29 CFR part 1926, subpart K) and General Industry (29 CFR part 1910, subpart S).	January 17, 2018, 83 FR 2468, Docket No. OSHA–2011–0187.	1218–0130	08/31/2021
General Working Conditions in Shipyard Employment Standard (29 CFR part 1915, subpart F).	October 2, 2017, 82 FR 45900, Docket No. OSHA–2014–0021.	1218–0259	02/28/2022
Marine Terminal Operations (29 CFR part 1917) and Longshoring (29 CFR part 1918) Standards.	February 5, 2019, 84 FR 1794, Docket No. OSHA–2012–0016.	1218–0196	07/31/2022
National Safety Stand-Down to Prevent Falls in Construction	January 12, 2018, 83 FR 1630, Docket No. OSHA–2017–0012.	1218–0271	06/30/2022
Occupational Exposure to Hazardous Chemicals in Laboratories (29 CFR 1910.1450).	October 26, 2018, 83 FR 54145, Docket No. OSHA–2011–0059.	1218–0131	06/30/2022
Occupational Safety and Health Act Variance Regulations (29 CFR 1905.10, 1905.11, and 1905.12).	March 30, 2018, 83 FR 13790, Docket No. OSHA–2009–0024.	1218–0265	02/28/2022
Occupational Safety and Health Onsite Consultation Agreements (29 CFR part 1908).	March 30, 2018, 83 FR 13792, Docket No. OSHA–2011–0125.	1218–0110	01/31/2022
Occupational Safety and Health State Plans	March 21, 2019, 84 FR 10551, Docket No. OSHA–2011–0197.	1218–0247	07/31/2022
OSHA Strategic Partnership Program for Workers Safety and Health	March 5, 2019, 84 FR 1791, Docket No. OSHA–2011–0861.	1218–0244	07/31/2022
Permit-Required Confined Spaces (29 CFR 1910.146)	May 22, 2018, 83 FR 23724, Docket No. OSHA–2011–0858.	1218–0203	10/31/2021
Personal Protective Equipment for Shipyard Employment (29 CFR part 1915, subpart I).	February 5, 2019, 84 FR 1795, Docket No. OSHA–2012–0038.	1218–0215	08/31/2022
Recordkeeping and Reporting Occupational Injuries and Illnesses (29 CFR part 1904).	July 29, 2019, 84 FR 36468, Docket No. OSHA–2013–0023.	1218–0176	03/31/2022
Reports of Injuries to Employees Operating Mechanical Power Presses (29 CFR 1910.217(g)).	April 19, 2018, 83 FR 17449, Docket No. OSHA–2012–0017.	1218–0070	02/28/2022
Shipyard Employment Standards (29 CFR part 1915)	April 11, 2018, 83 FR 15639, Docket No. OSHA–2011–0190.	1218–0220	08/31/2021
Slings Standard (29 CFR 1910.184)	January 17, 2018, 83 FR 2466, Docket No. OSHA–2011–0063.	1218–0223	08/31/2021
Telecommunications Standard (29 CFR 1910.268)	January 12, 2018, 83 FR 1632, Docket No. OSHA–2010–0057.	1218–0225	08/31/2021
Temporary Labor Camps (29 CFR 1910.142)	September 18, 2018, 83 FR 47190, Docket No. OSHA–2012–0012.	1218–0096	08/31/2022
Vehicle-Mounted Elevating and Rotating Work Platforms Standard (Aerial Lifts) (29 CFR 1910.67).	February 20, 2018, 83 FR 7235, Docket No. OSHA–2011–0185.	1218–0230	08/31/2021
Vertical Tandem Lifts for Marine Terminals (29 CFR part 1917)	January 22, 2018, 83 FR 3031, Docket No. OSHA–2011–0066.	1218–0260	08/31/2021

Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on October 18, 2019.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2019–23297 Filed 10–24–19; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2012–0034]

Hexavalent Chromium Standards; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend OMB approval of the information collection requirements specified in the Hexavalent Chromium standards for General Industry, Shipyard Employment, and Construction.

DATES: Comments must be submitted (postmarked, sent, or received) by December 24, 2019.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, including attachments, are not longer than 10 pages you may fax them to the OSHA Docket Office at (202) 693–1648.

Mail, hand delivery, express mail, messenger, or courier service: When

using this method, you must submit a copy of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2012–0034, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3653, 200 Constitution Avenue NW, Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the OSHA Docket Office's normal business hours, 10:00 a.m. to 3:00 p.m., ET.

Instructions: All submissions must include the agency name and the OSHA docket number (OSHA–2012–0034) for the Information Collection Request (ICR). All comments, including any personal information you provide, such as social security numbers and dates of birth, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov*. For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office at the above address. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at (202) 693–2222 to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of a continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance process to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, the reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (see 29 U.S.C. 657). The OSH Act also requires OSHA to obtain such information with a minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining said information (see 29 U.S.C. 657).

The information collection requirements in the Hexavalent Chromium standards for General Industry (29 CFR 1910.1026), Shipyard Employment (29 CFR 1915.1026), and Construction (29 CFR 1926.1126) (the ''standards'') protect workers from the adverse health effects that may result from occupational exposure to hexavalent chromium. The major information collection requirements in the standards include conducting worker exposure monitoring, notifying workers of their chromium exposures, implementing medical surveillance of workers, providing examining physicians with specific information, implementing a respiratory protection program, notifying laundry personnel of chromium hazards, and maintaining workers' exposure monitoring and medical surveillance records for specific periods.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply—for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

The agency is requesting an adjustment decrease of 72,001 burden hours (from 493,968 to 421,967 burden hours). The agency estimates an overall increase in the estimated number of covered establishments in specific industry sectors. However, due to the identification of a calculation error in the previous ICR, the burden hours associated with the establishment increase is off-set by a burden hour reduction associated with employee time to conduct quarterly exposure monitoring. In addition, there is an estimated decrease of $3,273,026 in operation and maintenance costs from $46,712,927 to $43,439,901. The decrease in these costs was due to a lower wage for contractors than the one used previously. This resulted in operating and maintenance costs that were lower than that reported in the previous ICR.

Type of Review: Extension of a currently approved collection.

Title: Hexavalent Chromium (Cr(VI)) Standards for General Industry (29 CFR 1910.1026), Shipyard Employment (29 CFR 1915.1026), and Construction (29 CFR 1926.1126).

OMB Control Number: 1218–0252.

Affected Public: Business or other for-profits.

Number of Respondents: 78,321.

Frequency: On occasion; Quarterly; Semi-annually; Annually.

Average Time per Response: Various.

Estimated Number of Responses: 923,898.

Estimated Total Burden Hours: 421,967.

Estimated Cost (Operation and Maintenance): $43,439,901.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number (Docket No. OSHA–2012–0034) for the ICR. You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify electronic comments by your name, date, and the docket number so that the agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the

delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693–2350; TTY (877) 889–5627.

Comments and submissions are posted without change at *http://www.regulations.gov*. Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office for information about materials not available through the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

Loren Sweatt, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on October 18, 2019.

Loren Sweatt,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2019–23296 Filed 10–24–19; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[NOTICE: (19–074)]

Notice of Availability of the Draft Supplemental Environmental Impact Statement (SEIS) for Soil Cleanup Activities at Santa Susana Field Laboratory

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of Availability of the Draft Supplemental Environmental Impact Statement (SEIS) to the March 2014 Final Environmental Impact Statement (FEIS) for demolition and environmental cleanup activities for the NASA-administered portion of the Santa Susana Field Laboratory (SSFL), Ventura County, California. This SEIS will cover the soil cleanup activities at NASA's portion of SSFL.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA), as amended, the Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA, and NASA's NEPA policy and procedures, NASA has prepared a Draft SEIS for soil cleanup activities at SSFL in Ventura County, California. The Draft SEIS has been prepared because there are significant new circumstances relevant to environmental concerns bearing on the proposed action and its impacts. Specifically, the estimated quantity of soil required to be removed has increased substantially since the publication of the 2014 FEIS. This increase has the potential to alter the environmental impacts that were evaluated in the 2014 FEIS. For this reason, NASA has determined it is appropriate to prepare a supplement to the 2014 FEIS.

DATES: Interested parties are invited to submit comments, preferably in writing, within forty-five (45) calendar days from the date of publication in the **Federal Register** of the Notice of Availability of the Draft SEIS on October 25, 2019.

ADDRESSES: Comments submitted by mail should be addressed to Peter Zorba, SSFL Project Director, 5800 Woolsey Canyon Road, Canoga Park, CA 91304. Comments may be submitted via email to *msfc-ssfl-eis@mail.nasa.gov.* The Draft SEIS may be reviewed at the following locations:

1. Simi Valley Library, 2969 Tapo Canyon Road, Simi Valley, CA 93063, Phone: (805) 526–1735.
2. Platt Library, 23600 Victory Blvd., Woodland Hills, CA 91367, Phone: (818) 340–9386.
3. California State University, Northridge Oviatt Library, 18111 Nordhoff Street, 2nd Floor, Room 265, Northridge, CA 91330, Phone: (818) 677–2285.
4. Department of Toxic Substances Control, 9211 Oakdale Avenue, Chatsworth, CA 91311, Phone: (818) 717–6521.

The Draft SEIS is also available on the internet at *https://www.nasa.gov/feature/environmental-impact-statement-eis-for-demolition-and-environmental-cleanup-activities.* The **Federal Register** Notice of Intent to prepare the Draft SEIS, issued in the **Federal Register** on April 5, 2019, is also available on the internet at: *https://ssfl.msfc.nasa.gov/news#news20190405.*

FOR FURTHER INFORMATION CONTACT: Peter Zorba, SSFL Project Director, by email at *msfc-ssfl-information@mail.nasa.gov.* Additional information about NASA's SSFL site, the proposed soil cleanup activities, and the associated planning process and documentation (as available) may be found on the internet at *https://ssfl.msfc.nasa.gov* or on the California Department of Toxic Substances Control (DTSC) website at *https://www.dtsc.ca.gov/SiteCleanup/Santa_Susana_Field_Lab/.*

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to announce the issuance and public availability of the Draft SEIS for review and comment, establish a 45 calendar day comment period, inform the public of where the document may be reviewed and comments can be submitted, and the date and time of public meetings. The Draft SEIS is intended to inform NASA decision makers, regulating agencies, and the public about the environmental impact of proposed soil cleanup in the NASA-administered portion of SSFL. The SSFL site is 2,850 acres located in Ventura County, California, approximately seven miles northwest of Canoga Park and approximately 30 miles northwest of downtown Los Angeles. SSFL is located near the crest of the Simi Hills, which are part of the Santa Monica Mountains running east-west across Southern California. The diverse terrain consists of ridges, canyons, and sandstone rock outcrops. SSFL is composed of four areas known as Areas I, II, III, and IV and two ''undeveloped'' areas. The NASA-administered portion is 41.7 acres within Area I and all 409.5 acres of Area II. The Boeing Company (Boeing) owns the remaining 2,398.8 acres within Areas I, III, IV, and the two undeveloped areas. The Department of Energy (DOE) is responsible for building demolition and cleanup of soils and groundwater in Area IV and the Northern Buffer Zone.

Since the mid-1950s, when the federal government portion of SSFL was administered by the U.S. Air Force, this site has been used for developing and testing rocket engines. Four test stand complexes were constructed in Area II between 1954 and 1957 named Alfa, Bravo, Coca, and Delta. These test stand areas along with the Liquid Oxygen (LOX) Plant portion of Area I were acquired by NASA from the U.S. Air Force in the 1970s.

The NASA-administered portion of SSFL contain historical and cultural resources associated with rocket development, along with a number of significant archeological sites. NASA has conducted several surveys to identify and locate archeological and architectural resources within its

administered portion of SSFL. NASA has identified the Burro Flats Cultural District, which is listed on the National Register of Historic Places (NRHP), as well as other various archeological sites, buildings, and structures that are either individually eligible for listing on the NRHP or are elements of NRHP-eligible historic districts containing multiple architectural resources. In 2014, NASA entered into a Programmatic Agreement with the California State Historic Preservation Officer, the Advisory Council for Historic Preservation, and the Santa Ynez Band of Chumash Indians. The Programmatic Agreement stipulates the cultural resource management measures that must be implemented before, during, and after all cleanup activities.

Environmental Commitments and Associated Environmental Review: Rocket engine testing has been discontinued at these sites and the property has been excessed to the General Services Administration (GSA). GSA has conditionally accepted the Report of Excess pending certain environmental cleanup requirements are met.

In 2007, a Consent Order among NASA, Boeing, the U.S. Department of Energy, and DTSC was signed addressing demolition of certain infrastructure and environmental cleanup of SSFL. NASA entered into an Administrative Order on Consent (AOC) for Remedial Action with DTSC on December 6, 2010, ''to further define and make more specific NASA's obligations with respect to the cleanup of soils at the Site.'' Based on the 2010 Order, NASA is required to complete a federal environmental review pursuant to NEPA and NASA Procedural Requirement (NPR) 8580.1.

NASA completed an FEIS for demolition of site infrastructure, soil cleanup, and groundwater remediation within Area II and a portion of Area I (former LOX Plant) of SSFL on March 14, 2014 (79 FR 14545). NASA subsequently issued a Record of Decision (ROD) for building demolition on April 25, 2014. A ROD for groundwater cleanup was published in the **Federal Register** on October 17, 2018. This Draft SEIS has been prepared by NASA for soil cleanup within its administered portion of SSFL.

Alternatives: NASA is committed to achieving an environmental cleanup that is protective of public health and the environment and the stewardship of the site's natural and cultural resources. The Draft SEIS considers the following range of alternatives that meet NASA's objectives to clean up soil at the portion of the SSFL site administered by NASA.

- Alternative A: Soil Cleanup to AOC Look Up Table (LUT) Values (similar to the Proposed Action from the 2014 FEIS with the impacts of increased soil volumes considered)
- Alternative B: Soil Cleanup to Revised AOC LUT Values (revisions to LUT values reflect standard California Water Board and California Human Health screening values)
- Alternative C: Soil Cleanup to Suburban Residential Cleanup Goals (based on the DTSC-approved Standardized Risk Assessment Methodology (SRAM) Revision 2 Addendum, U.S. Environmental Protection Agency (EPA) risk assessment guidelines for residential land use, and California Environmental Protection Agency (Cal EPA) risk assessment guidance)
- Alternative D: Soil Cleanup to Recreational Cleanup Goals (based on DTSC-approved SRAM Revision 2 Addendum, EPA risk assessment guidelines for recreational land use, and Cal EPA risk assessment guidance)

A No Action alternative, which is required per 40 CFR part 1500, was also included in the analysis, though it would not meet the cleanup goals.

Public Meetings: NASA plans to hold two public meetings to receive comments on the Draft SEIS regarding alternatives and environmental issues to be considered in the Final SEIS. The public meetings are scheduled as follows:

1. Best Western Posada Royale, Wednesday, November 20th, 2019 from 6:30–8:30 p.m., 1775 Madera Road, Simi Valley, CA 93065
2. Corporate Pointe at West Hill, Thursday, November 21st, 2019 from 6:30–8:30 p.m., 8411 Fallbrook Avenue, West Hills, CA 91304

NASA will consider all comments received in developing its Final SEIS; comments received and responses to comments will be included in the Final document. In conclusion, written public input on environmental issues and concerns associated with NASA's cleanup of SSFL are hereby requested.

Calvin F. Williams,

Assistant Administrator, Office of Strategic Infrastructure.

[FR Doc. 2019–23364 Filed 10–24–19; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[NOTICE: (19–073)]

National Environmental Policy Act; Mars 2020 Mission

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of availability for the Draft Supplemental Environmental Impact Statement (Supplemental EIS) for implementation of the Mars 2020 mission.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969 (NEPA), as amended, the Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA, and NASA's procedures for implementing NEPA, NASA announces the availability of the Draft supplement to the Final Environmental Impact Statement for the Mars 2020 Mission (Supplemental EIS) for public review and comment. The Draft Supplemental EIS provides updated information related to the potential environmental impacts associated with the proposed Mars 2020 mission.

FOR FURTHER INFORMATION CONTACT: Contact Mr. George Tahu by electronic mail at *mars2020-nepa@lists.nasa.gov* or by telephone at 202–358–0016.

SUPPLEMENTARY INFORMATION: The updated information is pertinent to the consequence and risk analyses of potential accidents which could occur during the launch phases of the mission. Although the probability of such accidents occurring is extremely small, it is possible that under certain conditions an accident could result in a release of plutonium dioxide from the Multi-Mission Radioisotope Thermoelectric Generator (MMRTG) into the environment. The MMRTG is a critical component of the Mars 2020 rover; it would enable the Mars 2020 rover mission to undertake a much broader scope of scientific discovery by providing a continuous supply of electrical power and temperature control to the Mars 2020 rover while on the surface of Mars. The Mars 2020 mission would launch the spacecraft onboard an Atlas V launch vehicle from the Cape Canaveral Air Force Station (CCAFS), Brevard County, Florida during the summer of 2020. Additional information about the mission may be found on the internet at: *https://mars.nasa.gov/mars2020/.*

NASA encourages all interested parties to provide comments concerning the scope and content of the Draft Supplemental EIS by December 10,

2019. The Draft Supplemental EIS is available in local libraries or for download on the internet at: *https://www.nasa.gov/feature/nepa-mars-2020-mission.*

NASA will also hold the following public meetings to solicit comments on the Draft Supplemental EIS:

November 13, 2019; 6 p.m.–9 p.m.: Kennedy Space Center Visitors Complex, Space Commerce Way, Merritt Island, FL 32953.

November 14, 2019; 2 p.m.–5 p.m.: Florida Solar Energy Center, 1679 Clearlake Rd., Cocoa, FL 32922.

November 15, 2019; 1 p.m.–3 p.m.: VIRTUAL meeting online at *http://go.nasa.gov/SEIS-meeting.*

At the meetings, NASA will describe the environmental review process, discuss the proposed action and the updated environmental analysis presented in the Draft Supplemental EIS, and provide the public an opportunity to offer comments. The meetings on November 13 and November 14 will begin with an open-house format for the first hour followed by a 20-minute formal presentation. After the formal presentation, there will be a public comment period in which members of the public may provide up to a three-minute statement. Written comments will also be collected throughout the meetings.

The meeting on November 15 will be a virtual meeting held at *http://go.nasa.gov/SEIS-meeting.*

A formal presentation will be given between 1:00 p.m.–1:20 p.m., thereafter attendees may then use the commenting feature to submit comments until 3 pm.

NASA will accept comments on the Draft Supplemental EIS until the expiration of the comment period on December 10, 2019. All comments NASA receives will be considered and responded to in the Final Supplemental EIS. Comments may be submitted at any of the public meetings, by electronic mail at *mars2020-nepa@lists.nasa.gov,* by telephone at 202–358–0016, or in writing to Mr. George Tahu, Planetary Science Division, Science Mission Directorate, Mail Suite 3E46, NASA Headquarters, Washington, DC 20546–0001.

Before including your address, phone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be publicly available at any time. While you can ask us in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

NASA's proposed Mars 2020 mission would use the proven design and technology developed for the Mars Science Laboratory mission and rover (Curiosity) that launched from CCAFS in November 2011 and arrived at Mars in August 2012. NASA has selected a high priority, scientifically important landing site based upon data from past and current missions. The rover is equipped with new scientific instrumentation that would: (a) Characterize the geological processes and history of an astrobiologically relevant ancient environment on Mars; (b) within the selected geological environment, assess the past habitability of the landing region and search for evidence of past life; (c) assemble a scientifically selected, well-documented, cache of samples for potential future return to the Earth; (d) further the preparation for future human exploration of Mars; and (e) demonstrate improved technical capabilities for landing and operating on the surface of Mars to benefit future Mars missions.

On September 11, 2013, NASA issued a Notice of Intent to prepare an Environmental Impact Statement (EIS) for the Mars 2020 mission. NASA prepared the EIS and issued the Final in November 2014. NASA evaluated several alternatives related to the Mars 2020 rover's power source. NASA identified use of the MMRTG as its preferred alternative to meet the mission's electrical, thermal, and operational requirements. Waste heat from the MMRTG would be used for temperature control of the rover electronics, science instruments, and other sensitive components. The MMRTG is identical to the power supply that has been used with success on the Mars Curiosity rover. Alternatives to the Proposed Action addressed in the 2014 Final EIS included: (1) The use of alternative sources of on-board power and heat (including solar energy); and (2) the No Action Alternative. The 2014 Mars 2020 Final EIS also addressed the purpose and need for the proposed Mars 2020 mission and the environmental impacts associated with its implementation. The environmental impacts associated with the normal launch of the mission were addressed, as were the potential consequences of launch related accidents. NASA issued its Record of Decision (ROD) for the Mars 2020 mission on January 27, 2015. The ROD adopted Alternative 1 as the preferred alternative. Alternative 1 required NASA to complete preparation for and implement the proposed Mars 2020 mission during July–August 2020, or during the next available launch opportunity in August through September 2022, and to operate the mission using a MMRTG that would continually provide heat and electrical power to the rover's battery. Since 2015, NASA has significantly advanced preparations for the Mars 2020 mission and selected the Atlas V as the launch vehicle. The Mars 2020 Final EIS discussed Incomplete and Unavailable Information which would be addressed in the future through more detailed risk analyses conducted as part of NASA's and the Department of Energy's (DOE) ongoing radiological safety review programs. These analyses were completed in 2019 and accounted for the Atlas V as the chosen launch vehicle (that was selected on August 25, 2016, after the Mars 2020 Record of Decision on January 27, 2015), up-to-date safety test information, and updated analytical models.

NASA policy for implementation of NEPA is found in NASA Procedural Requirements 8580.1A (NPR). The NPR requires preparation of a supplemental NEPA document when significant new information relevant to environmental concerns that bear on the proposed action or its impacts is discovered. Since NASA issued the 2014 Final EIS and 2015 ROD, the updated results from the risk and consequence modeling have become available for NASA's consideration. NASA has determined that the purposes of NEPA will be furthered by preparation and issuance of a Supplemental EIS.

Calvin F. Williams,

Associate Administrator, Office of Strategic Infrastructure, Mission Support Directorate.

[FR Doc. 2019–23363 Filed 10–24–19; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Notice of Antarctic Meteorite Collection, Documentation, and Curation Plan Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of Antarctic Meteorite Collection, Documentation, and Curation Plan received.

SUMMARY: On March 31, 2003, the National Science Foundation (NSF) issued a final rule that authorized the collection of meteorites in Antarctica for scientific purposes only. In addition, the regulations provide requirements for appropriate collection, handling, documentation, and curation of Antarctic meteorites to preserve their

scientific value. These regulations implement the Antarctic Conservation Act of 1978, as amended by the Antarctic Science, Tourism and Conservation Act of 1996, and Article 7 of the Protocol on Environmental Protection to the Antarctic Treaty. The NSF is required to publish notice of the availability of Meteorite Collection, Documentation, and Curation Plans received under the Antarctic Conservation Act of 1978. This is the required notice.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this plan by November 12, 2019. This plan may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, Virginia 22314.

FOR FURTHER INFORMATION CONTACT: Nature McGinn, ACA Permit Officer, at the above address, 703–292–8030, or *ACApermits@nsf.gov.*

SUPPLEMENTARY INFORMATION: An Antarctic meteorite collection, documentation, and curation plan has been received from James Karner of the University of Utah.

Erika N. Davis,

Program Specialist, Office of Polar Programs.

[FR Doc. 2019–23350 Filed 10–24–19; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting; National Science Board

The National Science Board's Awards and Facilities Committee, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

TIME & DATE: Thursday, October 31, 2019, from 5:00–6:00 p.m. EDT.

PLACE: This meeting will be held by teleconference at the National Science Foundation, 2415 Eisenhower Ave., Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda of the teleconference is: Committee Chair's Opening Remarks; Discussion of the principles underlying the solicitation for a future NEON operations and maintenance award.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Elise Lipkowitz, *elipkowi@nsf.gov,* telephone: (703) 292–7000. Meeting information and updates may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.* Please refer to the National Science Board website *www.nsf.gov/nsb* for general information.

Chris Blair,

Executive Assistant to the NSB Office.

[FR Doc. 2019–23412 Filed 10–23–19; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0122]

Program-Specific Guidance About Medical Use Licenses

AGENCY: Nuclear Regulatory Commission.

ACTION: NUREG; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued Revision 3 to NUREG–1556, Volume 9, ''Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.'' NUREG–1556 Volume 9 has been revised to include information on updated regulatory requirements, safety culture, security of radioactive materials, protection of sensitive information, and changes in regulatory policies and practices consistent with current regulations. This volume is intended for use by applicants, licensees, and the NRC staff.

DATES: NUREG 1556, Volume 9, Revision 3, was published in September 2019.

ADDRESSES: Please refer to Docket ID NRC 2016–0122 (NUREG–1556, Vol. 9, Rev. 3), 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–2016–0122. 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 ''*ADAMS Public Documents*'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* NUREG–1556, Volumes 9, Revision 3, is located at ADAMS Accession No. ML19256C219. This document is also available on the NRC's public website at *http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/* under ''Consolidated Guidance About Materials Licenses (NUREG–1556).''
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Dr. Katherine Tapp, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0236; email: *Katherine.Tapp@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC issued a revision to NUREG–1556, Volumes 9, to provide guidance to existing materials licensees covered under medical use licenses and to applicants preparing an application for a medical use license of byproduct material. This NUREG volume also provides the NRC staff with criteria for evaluating medical use license applications. The purpose of this notice is to notify the public that the NUREG–1556 volume listed in this document was issued as a final report.

II. Additional Information

The NRC published a notice of the availability of the draft report for comment version of NUREG–1556, Volume 9, Revision 3 in the **Federal Register** on December 6, 2016 (81 FR 87978), with an original public comment period of 63 days. The public comment period was extended for an additional 53 days on January 26, 2017 (82 FR 8545). The public comment period closed on March 31, 2017. Public comments and the NRC staff responses to the public comments for NUREG–1556, Volume 9, Revision 3 are available under ADAMS Accession No. ML18327A102.

III. Congressional Review Act

This NUREG volume 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 this NUREG revision to be a major rule as defined in the Congressional Review Act.

Dated at Rockville, Maryland, this 21st day of October 2019.

For the Nuclear Regulatory Commission.

Michael C. Layton,

Director, Division of Materials Safety, Security, State and Tribal Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2019–23316 Filed 10–24–19; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[EA–17–175/EA–18–183; NRC–2019–0210]

In the Matter of Dead Ringer, LLC

AGENCY: Nuclear Regulatory Commission.

ACTION: Order; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an Order to Dead Ringer, LLC, imposing a civil penalty of $43,500. On August 8, 2019, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty—$43,500 to Dead Ringer, LLC, for failing to comply with regulatory requirements regarding the import, possession, and distribution of gun sights containing radioactive material.

DATES: The Order imposing civil monetary penalty of $43,500 was issued on October 22, 2019.

ADDRESSES: Please refer to Docket ID NRC–2019–0210 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–2019–0210. Address questions about dockets IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–99127; 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 Document collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, 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 Order imposing civil monetary penalty is available in ADAMS under Accession No. ML19268A403.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Leelavathi Sreenivas, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555–001; telephone: 301–287–9249, email: *Leelavathi.Sreenivas@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the Order is attached.

Dated at Rockville, Maryland, this 22nd day of October 2019.

For the Nuclear Regulatory Commission.

George A. Wilson,

Director, Office of Enforcement.

Attachment—Order Imposing Civil Monetary Penalty

United States of America

Nuclear Regulatory Commission

In the Matter of: Dead Ringer, LLC, Rochester, NY.

EA–17–175
EA–18–183

Order Imposing Civil Monetary Penalty

I

Dead Ringer, LLC (Dead Ringer) provides tactical optics and sights, hunting scopes and sights, as well as archery broadheads, sights and accessories. Dead Ringer is located in Rochester, New York.

II

The U.S. Nuclear Regulatory Commission (NRC) initiated two separate investigations of Dead Ringer's activities on January 4, 2017, and January 19, 2018. The results of both investigations indicated that Dead Ringer had not conducted its activities in full compliance with the NRC's requirements associated with the initial transfer for sale or distribution of gun sights containing radioactive material (tritium). A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon Dead Ringer by letter dated August 8, 2019. The Notice states the nature of the violations, the provisions of the NRC's requirements that Dead Ringer violated, and the amount of the civil penalty proposed for the violations. As of the date of this Order, Dead Ringer has not responded to the Notice.

III

The NRC staff has determined that the violations occurred as stated and that the civil penalty in the amount of $43,500 should be imposed. In reaching this determination, the NRC staff considered that Dead Ringer was informed on August 8, 2019, of the NRC's enforcement decision and forthcoming Notice, which were transmitted electronically, as well as via certified mail. Additionally, the NRC staff informed Dead Ringer on September 10, 2019, that an Order would be forthcoming if the civil penalty was not paid. To date, Dead Ringer has not taken any action to address the Notice and proposed imposition of civil penalty.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and Title 10 of the *Code of Federal Regulations (10 CFR),* Part 2.205, *It is hereby ordered that:*

Dead Ringer pay a civil penalty in the amount of $43,500 within 20 days of the date of this Order. Payment is to be made in accordance with NUREG/BR–0254 ''Payment Methods'' (Enclosure 2). In addition, at the time payment is made, Dead Ringer shall submit a statement indicating when and by what method payment was made, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852–2738.

In accordance with 10 CFR 2.202 and 10 CFR 2.309, Dead Ringer must, and any other person adversely affected by this Order may, submit a response within 20 days of the issuance date of this Order. In addition, Dead Ringer or any other person adversely affected by this Order may request a hearing within 20 days of the issuance date of this Order. Where good cause is shown, consideration will be given to extending the time to respond or request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in

accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's Public website at *http://www.nrc.gov/site-help/e-submittalsgetting-started.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852. Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an Order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click ''Cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a person other than Dead Ringer requests a hearing, that person shall set forth with particularity the manner in which their interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f).

In the absence of any request for hearing, or written approval of an extension of time in which to request a hearing, the provisions specified in Section IV above shall be final 20 days from the issuance date of this Order without further order or proceedings. If an extension of time for requesting a hearing has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing request has not been received.

For the Nuclear Regulatory Commission

/RA/

George A. Wilson,

Director, Office of Enforcement

Dated this 22nd day of October, 2019.

[FR Doc. 2019–23315 Filed 10–24–19; 8:45 am]

BILLING CODE 7590–01–P

PEACE CORPS

Privacy Act of 1974: New System of Records

AGENCY: Peace Corps.

ACTION: Notice of a new system of records.

SUMMARY: Peace Corps proposes to add a new system of records to its inventory of records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. This action is necessary to meet the requirements of the Privacy Act to publish in the **Federal Register** notice of the existence and character of records maintained by the agency (5 U.S.C. 552a(e)(4)).

DATES: This action will be effective without further notice on December 4, 2019 unless comments are received that would result in a contrary determination.

ADDRESSES: Send written comments to the Peace Corps, ATTN: Virginia Burke, FOIA/Privacy Act Officer, 1111 20th Street NW, Washington, DC 20526 or by email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Virginia Burke, FOIA/Privacy Act Officer, 202–692–1887.

SUPPLEMENTARY INFORMATION: The purpose of this system of records is to maintain current Peace Corps personnel locator listings, and to notify Peace Corps personnel with specific, time-sensitive information before, during, and after an event, and to account for personnel who are affected by the event. Communication may be used for routine alerts, work-related issues, and emergency communications.

Dated: October 22, 2019.

Virginia Burke,

FOIA/Privacy Act Officer.

PC–36—PEACE CORPS

SYSTEM NAME:

Personnel Accountability System—Not Covered by Notices of Other Agencies.

SYSTEM LOCATION:

Peace Corps Headquarters, Peace Corps, 1111 20th Street NW, Washington, DC 20526.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Peace Corps domestic and overseas personnel which includes employees, contractors, interns, work study students, and Peace Corps Volunteers.

CATEGORIES OF RECORDS IN THE SYSTEM:

The agency-wide system covers all Peace Corps personnel accountability locator systems, emergency contact records and systems, telework contact records, or administrative contact lists not covered by OPM/GOVT–1 that contain Peace Corps personnel and organizational information. Information for Peace Corps personnel includes the individual's first name, last name, position staff title, employment type, work email address, work phone number, office location, home email address, personal phone number, unique Peace Corps staff identification number, photograph (optional), and country in which the individual works. Peace Corps Volunteer information includes personal email address, personal phone number, volunteer identification number, Post site location and residence address, and the longitude and latitude coordinates of the country site residence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations; 6 U.S.C. 501–521, National Emergency Management; as amended; 6 U.S.C. 572, National Emergency Communications Plan; Post-Katrina Emergency Management Reform Act of 2006, 6 U.S.C. 701, et. Seq., National Emergency Management; 22 U.S.C. 2501, et. seq., the Peace Corps Act; Public Law 87–293, as amended; 42 U.S.C. 5121–5207, the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended; National Security Presidential Directive—51 and Homeland Security Presidential Directive—20; Homeland Security Presidential Directive 12; Federal Continuity Directive 1; Executive Order (E.O.) 12137,The Peace Corps; E.O. 12472, Assignment of National Security and Emergency Preparedness Telecommunications Functions, as amended; E.O. 12656, Assignment of Emergency Preparedness Responsibilities; Peace Corps Manual Section (MS) 129, Office of the Chief Information Officer: Organization, Mission, and Functions; MS 130, Office of Safety and Security: Organization, Mission, and Functions; MS 132, Office of Human Resources: Organization, Mission, and Functions.

PURPOSE(S):

These records are used to maintain current Peace Corps personnel locator listings, and to notify Peace Corps personnel with specific, time-sensitive information before, during, and after an event, and to account for personnel who are affected by the event. Communication may be used for routine alerts, work-related issues, and emergency communications.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Peace Corps general routine uses A through M apply to this system.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, SECURING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in electronic media and paper.

RETRIEVABILITY—INFORMATION RETRIEVED USING THE FOLLOWING UNIQUE IDENTIFIER(S):

First name, last name, employment type, unique Peace Corps ID number, office name, position title, work or personal email account, and country or site in which the individual works.

SAFEGUARDS:

Records are centrally maintained in controlled areas within a secure facility. Physical entry is restricted by security guards and presentation of authenticated identification badges at entry control points, and key cards for access into buildings and authorized areas. Electronic records are maintained in a secured electronic system accessible only to authorized personnel responsible for maintaining the record system in the performance of their official duties. Access to computer data is managed by privileged management software and governing policies. Access is protected by an assigned user profile, user ID, password, encryption, and PIV card access on work computers. User profiles are role-based and ensure that the individual's role will only access authorized data. Paper records are maintained in locked file storage areas or in specified secured areas to which only authorized personnel have access.

RETENTION AND DISPOSAL:

Records are retained in accordance with the applicable NARA-approved retention schedules for temporary records. Disposal and destruction of electronic records is done by erasing, deleting, or overwriting the data. Paper records are destroyed by secure shredding.

SYSTEM MANAGER(S) AND ADDRESS:

Associate Director for Safety and Security; the Chief Information Officer; or the Chief Human Capital Officer, Peace Corps, 1111 20th Street NW, Washington, DC 20526.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records must send the written request to the Privacy Act Officer, Peace Corps, 1111 20th Street NW, Washington, DC 20526. Requesters will be required to provide adequate identification for verification purposes, such as a driver's license, employee identification card, or other identifying documentation. Additional identification may be required in some instances. The individual should reasonably specify the record contents being sought. Complete Peace Corps Privacy Act procedures are set out in 22 CFR part 308. Current Peace Corps

personnel may also directly access the particular system.

RECORD ACCESS PROCEDURES:

Active Peace Corps personnel have full access to and control over their individual record and may amend information at any time, or contact the System Manager. Individuals seeking to determine whether information about themselves is contained in this system of records must send the written request to the Privacy Act Officer Peace Corps, 1111 20th Street NW, Washington, DC 20526. Requesters will be required to provide adequate identification for verification purposes, such as a driver's license, employee identification card, or other identifying documentation. Additional identification may be required in some instances. The individual should reasonably specify the record contents being sought. All individuals requesting access must follow Peace Corps Privacy Act regulations regarding verification and identity. Complete Peace Corps Privacy Act procedures are set out in 22 CFR part 308.

CONTESTING RECORD PROCEDURES:

Active Peace Corps personnel have full access to and control over their individual record and may amend information at any time, or contact the System Manager. Any individual who wants to contest the contents of a record outside of their control should make a written request to the Privacy Act Officer at the address specified under notification procedures above. Requests for correction or amendment must reasonably identify the specific record to be changed, the information to be contested, and corrective action sought with supporting justification. Complete Peace Corps Privacy Act procedures are set out in 22 CFR part 308.

RECORD SOURCE CATEGORIES:

The information contained in this system is obtained from and updated by the individual on whom the record is maintained.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE PRIVACY ACT:

None.

[FR Doc. 2019–23387 Filed 10–24–19; 8:45 am]

BILLING CODE 6051–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87372; File No. SR–ISE–2019–30]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make Permanent Certain Options Market Rules That Are Linked to the Equity Market Plan To Address Extraordinary Market Volatility

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2019, Nasdaq ISE, 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 make permanent certain options market rules that are linked to the equity market Plan to Address Extraordinary Market Volatility.

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 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to make permanent certain options market rules in connection with the equity market Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or the ''Plan''). This change is being proposed in connection with the recently approved amendment to the Limit Up-Limit Down Plan that allows the Plan to continue to operate on a permanent basis (''Amendment 18'').[3] This proposed rule change is substantially similar to a recently-approved rule change by Cboe Exchange, Inc. (''Cboe'').[4]

In an attempt to address extraordinary market volatility in NMS Stocks, and, in particular, events like the severe volatility on May 6, 2010, U.S. national securities exchanges and the Financial Industry Regulatory Authority, Inc. (collectively, ''Participants'') drafted the Plan pursuant to Rule 608 of Regulation NMS and under the Act.[5] On May 31, 2012, the Commission approved the Plan, as amended, on a one-year pilot basis.[6] Though the Plan was primarily designed for equity markets, the Exchange believed it would, indirectly, potentially impact the options markets as well. Thus, the Exchange has previously adopted and amended Options 3, Section 9(d) and Supplementary Material .01 to Options 3, Section 20 to ensure the option markets were not harmed as a result of the Plan's implementation and has implemented such rules on a pilot basis that has coincided with the pilot period for the Plan (the ''Options Pilots'').[7] Options 3, Section 9(d) addresses the interplay of the Exchange's rules in response to the Plan, and includes

[3] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (Order Approving Amendment No. 18).

[4] *See* Securities Exchange Act Release Nos. 86744 (August 23, 2019), 84 FR 45565 (August 29, 2019) (SR–CBOE–2019–049) (Notice of Filing); and 87311 (October 15, 2019) (SR–CBOE–2019–049) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2). The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.

[5] *See* Securities Exchange Act Release No. 64547 (May 25, 2011), 76 FR 31647 (June 1, 2011) (File No. 4–631).

[6] *See* Securities and Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012).

[7] *See* Securities Exchange Act Release Nos. 69329 (April 5, 2013), 78 FR 21657 (April 11, 2014) (SR–ISE–2013–22); and 80432 (April 11, 2017), 82 FR 18191 (April 17, 2017) (SR–ISE–2017–03).

provisions on how the Exchange will treat certain options orders during a limit or straddle state as well as options market maker quoting obligations during a limit or straddle state. In addition, Supplementary Material .01 to Options 3, Section 20 provides that an execution will not be subject to obvious or catastrophic error review if it occurred during a limit or straddle state. A limit or straddle state occurs when at least one side of the National Best Bid (''NBB'') or Offer (''NBO'') bid/ask is priced at a non-tradable level. Specifically, a straddle state exists when the NBB is below the lower price band while the NBO is inside the prices band or when the NBO is above the upper price band and the NBB is within the band, while a limit state occurs when the NBO equals the lower price band (without crossing the NBB), or the NBB equals the upper price band (without crossing the NBO). The Exchange adopted the Options Pilots to protect investors because when an underlying security is in a limit up-limit down state, there will not be a reliable price for the security to serve as a benchmark for the price of the option. Specifically, the Exchange adopted Supplementary Material .01 to Options 3, Section 20 because the application of the obvious and catastrophic error rules would be impracticable given the potential for lack of a reliable NBBO in the options market during limit and straddle states. When adjusting or busting a trade pursuant to the obvious error rule, the determination of theoretical value of a trade generally references the NBB (for erroneous sell transactions) or NBO (for erroneous buy transactions) just prior to the trade in question, and is therefore not reliable when at least one side of the NBBO is priced at a non-tradeable level, as is the case in limit and straddle states. In such a situation, determining theoretical value may often times be a very subjective rather than an objective determination and could give rise to additional uncertainty and confusion for investors. As a result, application of the obvious and catastrophic error rules would be impracticable given the lack of a reliable NBBO in the options market during limit and straddle states, and may produce undesirable effects or unanticipated consequences. As noted above, the Exchange adopted additional measures via other Options Pilot rules that are designed to protect investors during limit and straddle states.[8] For example, the Exchange will reject Market Orders (as defined in Options 3, Section 7(a)) and cancel Stop Orders[9] during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state. Furthermore, the Exchange believes that eliminating the application of obvious error rules during a limit or straddle state eliminates the re-evaluation of a transaction executed during such a state that could potentially create an unreasonable adverse selection opportunity due to the lack of a reliable reference price on one side of the market or another and discourage participants from providing liquidity during limit and straddle states, which is contrary to the goal in limiting participants' adverse selection with the application of the obvious error rule during normal trading states. For these reasons, the Exchange believes the Options Pilots and related rules are designed to add certainty on the options markets, which encourages more investors to participate in light of the changes associated with the Plan. The Plan was originally implemented on a pilot-basis in order to allow the public, the participating exchanges, and the Commission to assess the operation of the Plan and whether the Plan should be modified prior to approval on a permanent basis. As stated, the Exchange adopted the Option Pilots to coincide with this pilot; to continue the protections therein while the industry gains further experience operating the Plan.

In connection with the order approving the establishment of the obvious error pilot, as well as the extensions of the obvious error pilot, the Exchange committed to submit monthly data regarding the program and to submit an overall analysis of the obvious error pilot in conjunction with the data submitted under the Plan and any other data as requested by the Commission. Pursuant to a rule filing, approved on April 7, 2014, each month, the Exchange committed to provide the Commission, and the public, a dataset containing the data for each straddle and limit state in optionable stocks that had at least one trade on the Exchange.[10] The Exchange has continued to provide the Commission with this data on a monthly basis. For each trade on the Exchange, the Exchange provides (a) the stock symbol, option symbol, time at the start of the straddle or limit state, an indicator for whether it is a straddle or limit state, and (b) for the trades on the Exchange, the executed volume, time-weighted quoted bid-ask spread, time-weighted average quoted depth at the bid, time-weighted average quoted depth at the offer, high execution price, low execution price, number of trades for which a request for review for error was received during straddle and limit states, an indicator variable for whether those options outlined above have a price change exceeding 30% during the underlying stock's limit or straddle state compared to the last available option price as reported by OPRA before the start of the limit or straddle state. In addition, to help evaluate the impact of the pilot program, the Exchange has provided to the Commission, and the public, assessments relating to the impact of the operation of the obvious error rules during limit and straddle states including: (1) An evaluation of the statistical and economic impact of limit and straddle states on liquidity and market quality in the options markets, and (2) an assessment of whether the lack of obvious error rules in effect during the straddle and limit states are problematic. The Exchange has concluded that the Options Pilots do not negatively impact market quality during normal market conditions,[11] and that there has been insufficient data to assess whether a lack of obvious error rules is problematic, however, the Exchange believes the continuation of the Options Pilots function to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets.

The Commission recently approved the Plan on a permanent basis (Amendment 18).[12] In connection with this approval, the Exchange now proposes to amend Options 3, Section 9(d) and Supplementary Material .01 to Options 3, Section 20 that currently implement provisions of the Plan on a pilot basis to eliminate the pilot basis, which effectiveness expires on October

[8] As set forth in Options 3, Section 9(d), this includes rules in connection with special handling for Market Orders and Stop Orders, and options market maker quoting obligations during a limit or straddle state.

[9] The Exchange will elect Stop Orders if the condition as provided in Options 3, Section 7(d) is met, and, because they become Market Orders, will then cancel them back. *See* Options 3, Section 9(d)(3).

[10] *See* Securities Exchange Act Release No. 71884 (April 7, 2014), 79 FR 20269 (April 11, 2014) (SR–ISE–2014–22); *see also* ISE LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.*

[11] *See also* ISE LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.* During the most recent Review Period the Exchange did not receive any obvious error review requests for Limit-Up-Limit Down trades, and Limit Up-Limit Down trade volume accounted for nominal overall trade volume.

[12] *See supra* note 3.

18, 2019, and to make such rules permanent. In its approval order to make the Plan permanent, the Commission recognized that, as a result of the Participants' and industry analysis of the Plan's operation, the Limit Up-Limit Down mechanism effectively addresses extraordinary market volatility. Indeed, the Plan benefits markets and market participants by helping to ensure orderly markets, but also, the Exchange believes, based on the data made available to the public and the Commission during the pilot period, that the obvious error pilot does not negatively impact market quality during normal market conditions.[13] Rather, the Exchange believes the obvious error pilot functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. The Exchange also believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders and cancel Stop Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[14] This removes impediments to and perfects the mechanism of a free and open market and national market system by encouraging more investors to participate in light of the changes associated with the Plan. The Exchange believes that if approved on a permanent basis, the Options Pilots would permanently provide investors with the above-described additional certainty of market prices and mitigation of unanticipated consequences and unreasonable adverse selection risk during limit and straddle states.

Since the Commission's approval of Amendment 18 allowing the Plan to operate on a permanent basis, the Exchange and other national securities exchanges have determined that no further amendments should be made to the Options Pilots;[15] the current Options Pilots effectively address extraordinary market volatility, are reasonably designed to comply with the requirements of the Plan, facilitate compliance with the Plan and should now operate on a permanent basis, consistent with the Plan. The Exchange does not propose any substantive or additional changes to Options 3, Section 9(d) or Supplementary Material .01 to Options 3, Section 20.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[16] in general, and Section 6(b)(5) of the Act,[17] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed rule supports the objectives of perfecting the mechanism of a free and open market and the national market system because it promotes transparency and uniformity across markets concerning rules for options markets adopted to coincide with the Plan. The Exchange believes that eliminating the pilot basis for the Options Pilots and making such rules permanent facilitates compliance with the Plan by adding certainty to the markets during periods of market volatility, which has been approved and found by the Commission to be reasonably designed to prevent potentially harmful price volatility in NMS Stocks. It has been determined by the Commission that the Plan benefits markets and market participants by helping to ensure orderly markets, and, based on the data made available to the public and the Commission during the pilot period for Supplementary Material .01 to Options 3, Section 20, the Plan does not negatively impact options market quality during normal market conditions. Rather, the Plan, as it is implemented under the obvious error pilot, functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. During a limit or straddle state, determining theoretical value of an option may be a subjective rather than an objective determination given the lack of a reliable NBBO, which may create an unreasonable adverse selection opportunity and discourage participants from providing liquidity during limit and straddle states. Therefore, the Exchange believes eliminating obvious error review in such states would, in turn, eliminate uncertainty and confusion for investors and benefit investors by encouraging more participation in light of the changes associated with the Plan. As stated, the Exchange believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders and cancel Stop Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[18] Accordingly, the Exchange believes that making the Options Pilots permanent will further the goals of investor protection and fair and orderly markets as the rules effectively address extraordinary market volatility pursuant to the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is necessary to reflect that the Plan no longer operates as a pilot and has been approved to operate on a permanent basis by the Commission. As such, Options 3, Section 9(d) and Supplementary Material .01 to Options 3, Section 20, which implement protections in connection with the Plan, should be amended to operate on a permanent basis. The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.[19] Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

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

[13] *See supra* note 11.

[14] *See supra* notes 8 and 9.

[15] *See* Securities Exchange Act Release No. 85605 (April 11, 2019), 84 FR 16098 (April 17, 2019) (SR–ISE–2019–10).

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *See supra* notes 8 and 9.

[19] In addition, the Exchange's proposal is substantially similar to Cboe's recently approved rule change. *See supra* note 4.

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 [20] and Rule 19b–4(f)(6) thereunder.[21]

A proposed rule change filed under Rule 19b–4(f)(6) [22] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [23] 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 proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current Options Pilots to continue on a permanent basis without any changes, prior to the pilot expiration on October 18, 2019. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[24]

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–2019–30 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–ISE–2019–30. 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–ISE–2019–30 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Eduardo A. Aleman,

Deputy Secretary.

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BILLING CODE 8011–01–P

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii).

[24] 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).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87377; File No. SR–CBOE–2019–099]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend and Consolidate Various Exchange Rules Relating to Trading Permit Holder Membership, Registration and Participants and Move Those Rules From the Currently Effective Rulebook to Proposed Chapter 3 of the Shell Structure for the Exchange's Rulebook That Will Become Effective Upon the Migration of the Exchange's Trading Platform to the Same System Used by the Cboe Affiliated Exchanges

October 21, 2019.

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 October 7, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] 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 and consolidate various Exchange Rules relating to Trading Permit Holder membership, registration and participants and move those Rules from the currently effective Rulebook to proposed Chapter 3 of the shell structure for the Exchange's Rulebook that will become effective upon the migration of the Exchange's trading platform to the same system used by the Cboe Affiliated Exchanges (as defined below) (''shell Rulebook''). The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

CBOELegalRegulatoryHome.aspx), at the Exchange's Office of the Secretary, 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

In 2016, the Exchange's parent company, Cboe Global Markets, Inc. (formerly named CBOE Holdings, Inc.) (''Cboe Global''), which is also the parent company of Cboe C2 Exchange, Inc. (''C2''), acquired Cboe EDGA Exchange, Inc. (''EDGA''), Cboe EDGX Exchange, Inc. (''EDGX'' or ''EDGX Options''), Cboe BZX Exchange, Inc. (''BZX'' or ''BZX Options''), and Cboe BYX Exchange, Inc. (''BYX'' and, together with Cboe Options, C2, EDGX, EDGA, and BZX, the ''Cboe Affiliated Exchanges''). Cboe Options intends to migrate its trading platform to the same system used by the Cboe Affiliated Exchanges, which the Exchange expects to complete on October 7, 2019 (the ''migration''). The Exchange proposes to amend certain registration-related rules, effective October 7, 2019. In connection with this technology migration, the Exchange has a shell Rulebook that resides alongside its current Rulebook, which shell Rulebook will contain the Rules that will be in place upon completion of the Cboe Options technology migration.

Also, in connection with the restructuring of the Exchange's Trading Permits, the Exchange proposes to modify its rules related to nominees and proposed Responsible Persons (current Rules 1.1, 3.1, 3.8, 3.9, 3.10, 3.19 and 17.6), as discussed more fully below. The Exchange also proposes to make non-substantive changes to simplify, clarify, and generally update its registration-related rules by consolidating various provisions and rules (including select rules not covered under current Chapter III but pertain to membership, registration and participants), deleting duplicative and obsolete rule provisions, reformatting provision sequencing, numbering, and lettering, and revising titles. The Exchange also updates cross-references to rules in the shell Rulebook that will be implemented upon migration. The table below lists each rule under current Chapter III, along with the few additional rules related to membership, registration and participants that the Exchange proposes to consolidate with the registration-related rules, the proposed rule in the shell Rulebook to which the current rule will be moved, whether the proposed change is substantive or non-substantive, and finally, a description of the proposed rule change. The Exchange notes that all current provisions proposed to move to the corresponding proposed provisions in the shell Rulebook will also be deleted from the current rules upon migration.

Current rule	Proposed rule	Substantive change	Description of change
N/A	Rule 1.1 (Nominee defined)	Y: see further discussion below.	Updates the nominee definition to provide that a nominee represents TPH organization in all matters relating to the Exchange with respect to a Floor Broker or Market-Maker Floor Trading Permit, as more fully described below
N/A	Rule 1.1 (Responsible Person defined).	Y: see further discussion below.	Adopts definition of a ''Responsible Person'' as described more fully below.
Rule 3.1 (Trading Permits)	Rule 3.1 (Trading Permits)	N	Moves rule in its entirety. Adds references to ''Responsible Persons'' in light of proposed rule change. Eliminates language regarding separate Trading Permits for RTH and GTH in current Rule 3.1(a)(iv) as post-migration electronic Trading Permits provide access to both sessions. Renumbers provisions and updates cross-references.
Rule 3.1A (Issuance of Trading Permits in Respect of Memberships and Pre-Restructuring Transaction Trading Permits).	N/A (deleted)	N	Deletes obsolete rules that previously governed the issuance of Trading Permits in connection with the prior restructuring of the Exchange from a non-stock corporation to a stock corporation and wholly owned subsidiary of Cboe Global Markets, Inc.
Rule 3.2 (Qualifications of Individual Trading Permit Holders).	Rule 3.2 (Qualifications of Individual TPH).	N	Moves rule in its entirety. Renumbers provisions and updates title.
Rule 3.3 (Qualifications of TPH organizations).	Rule 3.3 (Qualifications of TPH Organizations).	N	Moves rule in its entirety. Renumbers provisions.
Rule 3.4 (Foreign Trading Permit Holders).	Rule 3.4 (Foreign TPHs)	N	Moves rule in its entirety. Updates title.
Rule 3.4A (Additional Trading Permit Holder Qualifications).	Rule 3.5 (Additional TPH Qualifications).	N	Moves rule in its entirety. Renumbers provisions and updates title.
Rule 3.5 (Denial of and Conditions to Being a Trading Permit Holder or Associated with a Trading Permit Holder).	Rule 3.6 (Denial of and Conditions to Being a TPH or Associated with a TPH).	N	Moves rule in its entirety. Renumbers provisions and updates cross-references and title.
Rule 3.6 (Persons Associated with TPH Organizations).	Rule 3.7 (Persons Associated with TPH Organizations).	N	Moves rule in its entirety.

Current rule	Proposed rule	Substantive change	Description of change
Rule 3.6A (Qualification and Registration of Trading Permit Holders and Associated Persons).	Rule 3.30 (Qualifications and Registration of TPHs and Associated Persons).	N	Moves rule in its entirety. Renumbers provisions and updates cross-references and title.
Rule 3.7 (Certain Documents Required of Trading Permit Holders, Applicants, and Associated Persons).	Rule 3.8 (Certain Documents Required of TPHs, Applications and Associated Persons).	N	Moves rule in its entirety. Renumbers provisions and updates cross-references and title.
Rule 3.8 (Nominees)	Rule 3.9 (Responsible Persons and Nominees).	Y: see further discussion below.	Moves rule in its entirety. Adopts concept of ''Responsible Person''. Amends and updates Rule accordingly, as described more fully below. Renumbers provisions, eliminates redundant provisions, and updates cross-references and title.
Rule 3.9 (Application Procedures and Approval or Disapproval).	Rule 3.10 (Application Procedures and Approval or Disapproval).	N	Moves rule in its entirety. Adds references to ''Responsible Persons'' and ''nominees''. Updates cross-references.
Rule 3.10 (Effectiveness of Trading Permit Holder or Approved Associated Person Status).	Rule 3.11 (Effectiveness of PTH or Approved Associated Person Status).	N	Moves rule in its entirety. Adds references to ''Responsible Persons'' and ''nominees''. Updates cross-reference and title.
Rule 3.11 (Affiliation Between the Exchange and a Trading Permit Holder).	Rule 3.62 (Affiliation Between the Exchange and a TPH).	N	Moves rule in its entirety. Updates title.
Rule 3.12 (Cboe Trading as Outbound Router).	Rule 3.63 (Cboe Trading as Outbound Router).	N	Moves rule in its entirety.
Rule 3.13 (Cboe Trading as Inbound Router).	Rule 3.64 (Cboe Trading as Inbound Router).	N	Moves rule in its entirety.
Rule 3.14 (Reserved)	N/A (deleted)	N	Deletes reserved rule.
Rule 3.15 (Reserved)	N/A (deleted)	N	Deletes reserved rule.
Rule 3.16 (Reserved)	N/A (deleted)	N	Deletes reserved rule.
Rule 3.17 (Reserved)	N/A (deleted)	N	Deletes reserved rule.
Rule 3.18 (Trading Permit Holders and Associated Persons Who Are or Become Subject to a Statutory Disqualification).	Rule 3.13 (TPHs and Associated Persons Who Are or Become Subject to a Statutory Disqualification).	N	Moves rule in its entirety. Updates cross-references and title.
Rule 3.19 (Termination from Trading Permit Holder Status).	Rule 3.14 (Termination from TPH Status).	N	Moves rule in its entirety. Adds reference to ''Responsible Person''. Updates title.
Rule 3.20 (Dissolution and Liquidation of TPH Organizations).	Rule 3.15 (Dissolution and Liquidation of TPH Organizations).	N	Moves rule in its entirety. Updates cross-reference.
Rule 3.21 (Obligations of Terminating Trading Permit Holders).	Rule 3.16 (Obligations of Terminating TPHs).	N	Moves in its entirety. Updates title.
Rule 3.22 (Reserved)	N/A (deleted)	N	Deletes reserved rule.
Rule 3.24 (Reserved)	N/A (deleted)	N	Deletes reserved rule.
Rule 3.25 (Reserved)	N/A (deleted)	N	Deletes reserved rule.
Rule 3.26 (Reserved)	N/A (deleted)	N	Deletes reserved rule.
Rule 3.27 (Reserved)	N/A (deleted)	N	Deletes reserved rule.
Rule 3.28 (Letters of Guarantee and Authorization).	Rule 3.61 (Letters of Guarantee and Authorization).	N	Moves rule in its entirety. New provisions added from other rules, as described more fully below. Clarify in new Rule 3.61(a) that TPHs must have a letter of guarantee from a Clearing Trading Permit Holder that is properly authorized by the Options Clearing Corporation (''OCC'') to operate during the GTH session, which is required currently today. Renumbers provisions.
Rule 3.29 (Membership in OneChicago, LLC).	Rule 3.65 (Membership in OneChicago, LLC).	N	Moves rule in its entirety.
Rule 3.30 (Extension of Time Limits).	Rule 3.17 (Extension of Time Limits).	N	Moves rule in its entirety.
Rule 3.31 (Reserved)	N/A (deleted)	N	Deletes reserved rule.
Rule 3.32 (Ownership Concentration and Affiliation Limitation).	Rule 3.18 (Ownership Concentration and Affiliation Limitation).	N	Moves rule in its entirety.
Rule 6.20A (Sponsored Users)	Rule 3.60 (Sponsored Users)	N	Moves rule in its entirety. Eliminates reference to FLEX Hybrid Trading System in current Rule 6.20A .01 as FLEX will no longer trade on that system post-migration, but rather the same system as all other trading on Cboe Options. Renumbers provisions and updates cross-references.
Rule 6.70 (Floor Broker Defined) Rule 6.71 (Registration of Floor Brokers).	Rule 3.50 (Floor Brokers)	N	Current Rule 6.70 moves to new Rule 3.50(a). Current Rule 6.71 moves to new Rule 3.50(b). Renumbers provisions and updates cross-references. Updates title.

Current rule	Proposed rule	Substantive change	Description of change
Rule 6.72 (Letters of Authorization).	Rule 3.61 (Letters of Guarantee and Authorization).	N	Moves to Rule 3.61(b); eliminates provisions in current rule 6.72(c) and (d) as such provisions are redundant to provisions already covered by current Rule 3.28 (and now new rule 3.61(a)). Renames ''Letter of Authorization'' to ''Letter of Guarantee'' for consistency.
Rule 6.77 (Order Service Firms)	Rule 3.59 (Order Service Firms)	N	Moves rule in its entirety.
Rule 6.78 (Letters of Guarantee Required of Order Service Firms).	Rule 3.61 (Letters of Guarantee and Authorization).	N	Moves to Rule 3.61(d); eliminates subparagraph (c) as such provision is redundant to provision already in current Rule 3.28 (and now new rule 3.61(a)).
Rule 8.5 (Letters of Guarantee)	Rule 3.61 (Letters of Guarantee and Authorization).	N	Moves to Rule 3.61(b); eliminates subparagraph (c) as such provision is redundant to provision already in current Rule 3.28 (and now new rule 3.61(a)).
Rule 24A.13 (Letter of Guarantee or Authorization).	Rule 3.61 (Letters of Guarantee and Authorization).	N	Moves to Rule 3.61(e); eliminates subparagraph (c) as not necessary in light of consolidated rule.
N/A	Rule 3.51 (OEFs)	N	Adopts definition of ''OEF'' from Rule 1.1 (Definitions) in shell rulebook.
N/A	13.6	N	Adds reference to ''Responsible Person''.

Other than the proposed changes regarding Responsible Persons, described more fully below, the proposed rules are virtually identical (renumbering or reorganizing paragraphs, updating cross-references and titles, and making the types of non-substantive or clarifying changes as described above), and are merely moving from the current Rulebook to the shell Rulebook. The Exchange intends to move the current rules indicated above to proposed Chapter 3 of the shell Rulebook in order to consolidate into one location the rules that relate to membership, registration and participants.

Responsible Persons

As noted above, in connection with the migration, the Exchange intends to modify its current Trading Permit structure. By way of background, current Cboe Option Rule 1.1 defines a Trading Permit as a license issued by the Exchange that grants the holder or the holder's nominee the right to access one or more of the facilities of the Exchange for the purpose of effecting transactions in securities traded on the Exchange without the services of another person acting as broker, and otherwise to access the facilities of the Exchange for purposes of trading or reporting transactions or transmitting orders or quotations in securities traded on the Exchange, or to engage in other activities that, under Cboe Options Rules, may only be engaged in by Trading Permit Holders, provided that the holder or the holder's nominee, as applicable, satisfies any applicable qualification requirements to exercise those rights.[5] The Exchange may issue different types of Trading Permits and determine the fees for those Trading Permits.[6] The Exchange currently maintains three types of Trading Permits. Particularly, the Exchange offers a Market-Maker Trading Permit, a Floor Broker Trading Permit and an Electronic Access Permit. The Exchange also offers separate Market-Maker and Electronic Access Permit for the Global Trading Hours (''GTH'') session. More specifically, Market-Maker trading Permits entitle the holder to act as a Market-Maker, including a Market-Maker trading remotely, DPM, eDPM, or LMM, and also provides an appointment credit of 1.0, a quoting and order entry bandwidth allowance, up to three logins, trading floor access and TPH status.[7] A Floor Broker Trading Permit entitles the holder to act as a Floor broker, provides an order entry bandwidth allowance, up to 3 logins, trading floor access and TPH status.[8] Lastly, an Electronic Access Permit (''EAP'') entitles the holder to electronic access to the Exchange. Holders of EAPs must be broker-dealers registered with the Exchange in one or more of the following capacities: (a) Clearing TPH, (b) TPH organization approved to transact business with the public, (c) Proprietary TPHs and (d) order service firms. The permit does not provide access to the trading floor. An EAP also provides an order entry bandwidth allowance, up to 3 logins and TPH status.[9] In addition, Rule 3.1(a)(v) provides, in relevant part, that Trading Permits will be subject to such fees and charges as are established by the Exchange from time to time pursuant to Exchange Rule 2.1 and the Exchange Fees Schedule.[10]

As noted above, Trading Permits are currently tied to bandwidth allocation, logins and appointment costs, and as such, TPH organizations may hold multiple Trading Permits of the same type in order to meet their connectivity needs. Post-Migration, bandwidth allocation, logins and appointment costs will no longer be tied to a Trading Permit, and as such, the Exchange is modifying its Trading Permit structure. Specifically, post-Migration, the Exchange will issue five types of Trading Permits; an electronic Market-Maker Permit, an Electronic Access Permit, a Clearing TPH Permit, a Market-Maker Floor Permit and a Floor Broker Permit.[11] More specifically, the Exchange will provide that for electronic access to the Exchange, a TPH need only purchase one of the following permit types for each trading function the TPH intends to perform: Market-Maker Electronic Access Permit (''MM EAP'') in order to act as an off-floor Market-Maker, Electronic Access Permit (''EAP'') in order to submit orders

[5] A Trading Permit does not convey any ownership interest in the Exchange, is only available through the Exchange, and is subject to the terms and conditions set forth in Cboe Options Rule 3.1.

[6] *See* Cboe Options Rule 3.1(v).

[7] *See* Cboe Options Fees Schedule.

[8] *Id.*

[9] *Id.*

[10] The Exchange has submitted a separate rule filing to amend Trading Permit fees. *See* SR–CBOE–2019–082.

[11] Cboe Option Rules provides the Exchange authority to issue different types of Trading Permits which allows holders, among other things, to act in one or more trading functions authorized by the Rules. *See* Cboe Options Rule 3.1(a)(iv).

electronically to the Exchange,[12] and a Clearing TPH Permit, for TPHs approved solely as a Clearing TPH.[13] Additionally, as part of the migration the Exchange is eliminating Global Trading Hours Trading Permits. Instead, the Exchange will provide that any MM EAP, EAP and Clearing TPH Permit provides access (at no additional cost) to the GTH session.[14] Post-migration, the Exchange will have separate Trading Permits for on-floor and off-floor activity. As such, the Exchange will be maintaining a Floor Broker Trading Permit (''FB Permit'') and adopting a new Market-Maker Floor Permit (''MM Floor Permit'') for on-floor Market-Makers. Floor-based permits may only be tied to one individual (*i.e.,* nominee) at a time.

In light of the restructuring of the Exchange's Trading Permits, the Exchange therefore proposes to modify its rules related to nominees. Currently, a TPH organization must designate an individual nominee to represent the organization with respect to that Trading Permit in all matters relating to the Exchange, provided that in the case of a Trading Permit held in the name of an individual, the TPH organization shall be required to designate that individual as the nominee for that Trading Permit.[15] Additionally, in the situation where the TPH organization is holding multiple Trading Permits in its name, the TPH organization may designate the same individual to be a nominee for those Trading Permits.[16] Moreover, each nominee of a TPH organization, except for a nominee of a TPH organization approved solely as a Clearing Trading Permit Holder and/or to transact business with the public pursuant to current Rule 9.1, is required to have an authorized trading function.[17] Among other requirements, a nominee is required to be materially involved in the daily operation of the Exchange business activities of the TPH organization for which the person is a nominee; have authorized trading functions only on behalf of one TPH organization; and perform trading functions only on behalf of the TPH organization for which the person is approved by the Exchange to perform such functions and may not perform trading functions on the person's own behalf or on behalf of another TPH organization.[18]

Post-migration the Exchange proposes to provide that only floor-based Trading Permits (*i.e.,* MM Floor and FB Permits) require the designation of a nominee. In lieu of nominees, TPH organizations that hold electronic permits (*i.e.,* MM EAPs, EAPs and Clearing TPH Permits) will be required to designate at least one ''Responsible Person''. The Responsible Person will be required to be affiliated with the TPH and shall represent the organization with respect to a TPH's electronic Trading Permit(s) in all matters relating to the Exchange. The Responsible Person must be a U.S.-based officer, director or management-level employee of the TPH, who is responsible for the direct supervision and control of Associated Persons of that TPH. A Responsible Person for a Foreign Trading Permit Holder does not need to be U.S.-based, but must be an individual registered in Web CRD.[19] The Exchange notes that its affiliate C2 similarly requires the designation of a Responsible Person.[20] In connection with the proposed change, the Exchange proposes to amend its nominee rule (current Rule 3.8, proposed new Rule 3.9) to adopt new subparagraph 3.9(a), which will set forth the requirements relating to Responsible Persons, as well as add corresponding references to Responsible Persons in the remaining provisions of proposed Rule 3.9. Proposed Rule 3.9(a) is substantially similar to C2's corresponding rule.[21]

With respect to floor-based permits, the Exchange will still require the designation of a nominee per permit. Particularly, proposed subparagraph (b) will provide that each TPH organization that is holder of a FB Permit or MM Floor Permit must designate an individual nominee to represent the organization with respect to each FB Permit or MM Floor Permit in all matters relating to the Exchange. As noted above, each FB Permit and MM Floor Permit may only be tied to one individual at a time.[22] As such, the Exchange proposes to eliminate the language in current Rule 3.8(a)(ii) which allows a TPH to designate the same individual to be a nominee for its Trading Permits. The Exchange notes however, that a nominee of a TPH may also be designated as a Responsible Person with respect to a TPH's electronic Trading Permits so long as such nominee satisfies the proposed requirements of being a Responsible Person. Similarly, a Responsible Person may also be designated as a nominee for a TPH's floor Trading Permits so long as such person satisfies the requirements of being a nominee. A TPH organization may never have more individuals (*i.e.,* nominees) on the floor than it has floor-based Trading Permits. Further, each nominee must be registered as a Floor Broker if acting as a nominee on behalf of a FB Permit and registered as a Market-Maker if acting as a nominee on behalf of a MM Floor Permit. As is the case today, a nominee may have authorized trading functions only on behalf of one TPH organization and may perform trading functions only on behalf of the TPH organization for which the person is approved by the Exchange to perform such functions and may not perform trading functions on the person's own behalf or on behalf of another TPH organization.[23] As nominees will be required to be registered as either a Floor Broker or Market-Maker, the Exchange believes the requirement under current Rule 3.8(c)(i) to be materially involved in the daily operation of the Exchange activities of the TPH organization is no longer necessary and as such the Exchange proposes to delete such provision.[24] The Exchange also proposes to eliminate current subparagraph 3.8(a)(v), which provides each nominee of a TPH organization who is approved to be a Trading Permit Holder shall be deemed to be an individual Trading Permit Holder. The Exchange believes this point is already made clear current (and proposed) Rule

[12] EAPs may be purchased by TPHs that both clear transactions for other TPHs (*i.e.,* a ''Clearing TPH'') and submit orders electronically.

[13] Currently any TPH that is registered to act as a Clearing TPH must purchase an Electronic Access Permit, whether or not that Clearing TPH acts solely as a Clearing TPH or acts as a Clearing TPH and submits orders electronically. The Exchange proposes to adopt a new Trading Permit, for any TPH that is registered to act solely as Clearing TPH. Clearing TPHs that both clear transactions for other TPHs and that are approved in a capacity to submit orders electronically to the Exchange need only obtain the proposed EAP.

[14] Clearing TPHs must be properly authorized by the Options Clearing Corporation (''OCC'') to operate during the GTH session. As such, in order to participate in GTH, a TPH must have a Letter of Guarantee on file from a Clearing TPH that is authorized to operate during GTH. The Exchange proposes to amend proposed Rule 3.61 (current Rule 3.28), to make this point clear in the rules.

[15] *See* Current Cboe Options Rule 3.8(a)(i).

[16] *See* Current Cboe Options Rule 3.8(a)(ii).

[17] *See* Current Cboe Options Rule 3.8(a)(iii).

[18] *See* Current Cboe Options Rule 3.8(c).

[19] The Exchange notes that for Foreign TPHs, the requirement that the individual be U.S.-based is waived as such TPHs may not have an individual that meets all of the proposed requirements based in the U.S.

[20] *See* C2 Rule 1.1 (''Responsible Person'') and Rule 3.8 (Responsible Person).

[21] *See* C2 Rule 1.1 (''Responsible Person'') and Rule 3.8 (Responsible Person).

[22] TPHs may continue to designate and maintain ''inactive nominees'' pursuant to proposed Rule 3.9(e) (current Rule 3.8(e)).

[23] The Exchange proposes to relocate these provisions from current Cboe Options Rule 3.8(c)(ii)–(iii) to new subparagraph (b) of proposed Rule 3.9, making the rule easier to follow.

[24] Given the proposed deletion of the language in current Rule 3.8(c)(i) and the relocation of current subparagraphs (c)(ii) and (c)(iii), current Rule 3.8(c) will be eliminated in its entirety.

3.2 which provides ''An individual must satisfy the following requirements in order to be an individual Trading Permit Holder, whether in the capacity of a holder of a Trading Permit or a nominee of a TPH'' and as such the proposed language is redundant and unnecessary.

In connection with the proposed changes relating to Responsible Persons and nominees, the Exchange proposes to also amend other exchange rules. Particularly, the Exchange proposes to amend the following rules: (1) Proposed Rule 3.1 (currently Rule 3.1), to provide Responsible Persons, in addition to nominees, are subject to the regulatory jurisdiction of the Exchange and that a TPH organization may change the designation of Responsible Persons in addition to nominees with respect to its Trading Permits; (2) proposed Rule 3.10 (currently Rule 3.9) to clarify that any individual that is designated as a nominee or Responsible Person must submit an application and be investigated, in accordance with the rule; (3) proposed Rule 3.11 (currently Rule 3.10) to clarify that each Responsible Person and nominee must become effective within 90 days of the date of the applicant's approval for such status; (4) proposed Rule 3.14 (currently Rule 3.19) to clarify that a TPH's status may be automatically terminated if it has no Responsible Person or nominee; and (5) proposed Rule 13.6 (currently Rule 17.6) to provide that a Responsible Person or nominee may represent a TPH organization in a hearing.

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) of the Act.[25] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[26] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[27] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed rule changes will remove impediments to and perfect the mechanism of a free and open market and a national market system by providing for a more streamlined and simplified permit structure and rules relating to nominees and proposed Responsible Persons. Particularly, post-migration, the new connectivity and permit structure will eliminate the need for TPHs to hold multiple permits for purposes of appointment costs, logins and/or bandwidth and will provide clear distinctions between off-floor and on-floor permits and the individual representatives of such permits (*i.e.,* nominees and Responsible Persons). The Exchange believes the proposal to require TPHs to designate a Responsible Person, instead of a nominee, for such Trading Permits therefore provides for a more straightforward administration of the Exchange's permit structure. Indeed, the proposed change more closely aligns the Exchange's membership requirements with those of its affiliate exchange, C2, which has a similar electronic permit structure as proposed and is on the same platform the Exchange is migrating to.[28] The Exchange believes its proposal to adopt Responsible Persons therefore provides greater uniformity of the Exchange's rules and its affiliated exchange and therefore less burdensome and more efficient regulatory compliance. The proposed definition of a Responsible Persons is also substantially the same as other exchanges that have a similar requirement.[29] The Exchange notes that similar to a designated nominee, Responsible Persons will represent the organization with respect to each electronic Trading Permit in all matters relating to the Exchange. As such, every TPH organization, whether participating electronically or on the floor of the Exchange, will continue to have a designated individual that represents the Exchange, and has gone through an application and investigation process.

The Exchange notes that it is not substantively changing any rights or obligations of nominees of floor Trading Permits. Rather, the Exchange merely is proposing to update its rules to reflect that nominees will, upon migration, only represent a FB Trading Permit or MM Floor Trading Permit and therefore must only be registered as a FB or MM, respectively. The Exchange believes the proposed changes to its nominee rule (current Rule 3.8, proposed Rule 3.9) also alleviates confusion by reorganizing and consolidating provisions, simplifying language, and removing redundancies.

As stated, the proposed rule changes not related to Responsible Persons makes no substantive changes to the rules. Rather, those proposed rule changes are merely intended to make the types of non-substantive or clarifying changes as described in the table and discussion above and relocate the Exchange's rules to the shell Rulebook and update their numbers, paragraph structure, including number and lettering format, and cross-references to conform to the shell Rulebook as a whole in anticipation of the technology migration on October 7, 2019. As such, the proposed rule change 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 improving the way the Exchange's Rulebook is organized, making it easier to read, and, particularly, helping market participants better understand the rules of the Exchange, which will also result in less burdensome and more efficient regulatory compliance.

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. Particularly, the Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because the proposed changes apply to all TPHs. The proposed rule change also does not address competitive issues, but rather, amends its requirements relating to nominees in connection with the upcoming technology migration and resulting change in the Exchange's Trading Permit structure and/or makes non-substantive rule changes in relocating the rules and updating cross-references to shell rules in anticipation of the October 7, 2019 technology migration. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the

[25] 15 U.S.C. 78f(b).

[26] 15 U.S.C. 78f(b)(5).

[27] *Id.*

[28] *See* C2 Rules1.1 (''Responsible Person'') and 3.8 (Responsible Person).

[29] *See e.g.,* MIAX Options Rules 100 and 207.

purposes of the Act because the proposed change only affects TPHs of Cboe Options and those applying for membership to Cboe Options. To the extent that the proposed change makes Cboe Options a more attractive marketplace for market participants at other exchanges, such market participants are welcome to become Cboe Options market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received 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)(3)(A) of the Act [30] and Rule 19b–4(f)(6) thereunder.[31]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [32] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [33] 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 Exchange may implement the proposed rule change at the time of its anticipated October 7, 2019 system migration. The Exchange believes that waiver of the operative delay is appropriate because, as the Exchange discussed above, its proposal does not make any substantive changes to the Exchange's rules. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal does not raise any new or novel issues and makes only non-substantive changes to the rules. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.[34]

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 will 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–CBOE–2019–099 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–CBOE–2019–099. 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–CBOE–2019–099 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[35]

Eduardo A. Aleman,

Deputy Secretary.

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BILLING CODE 8011–01–P

[30] 15 U.S.C. 78s(b)(3)(A).

[31] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[32] 17 CFR 240.19b–4(f)(6).

[33] 17 CFR 240.19b–4(f)(6)(iii).

[34] 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).

[35] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87375; File No. SR–BOX–2019–31]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule IM–7170–1, To Make Permanent the Exchange Rule That Is Linked to the Equity Market Plan To Address Extraordinary Market Volatility

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2019, BOX Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule IM–7170–1, to make permanent the Exchange Rule that is linked to the equity market Plan to Address Extraordinary Market Volatility

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(the ''Limit Up-Limit Down Plan'' or the ''Plan''). The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at *http://boxoptions.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend BOX Rule IM–7170–1 to make permanent the Exchange Rule that is connected to the Plan. This change is being proposed in connection with the recently approved amendment to the Limit Up-Limit Down Plan that allows the Plan to continue to operate on a permanent basis (''Amendment 18'').[3]

In an attempt to address extraordinary market volatility in NMS stocks, and, in particular, events like the severe volatility on May 6, 2010, U.S. national securities exchanges and the Financial Industry Regulatory Authority, Inc. (collectively, ''Participants'') drafted the Plan pursuant to Rule 608 of Regulation NMS under the Act.[4] On May 31, 2012, the Commission approved the Plan, as amended, on a one-year pilot basis.[5] Though the Plan was primarily designed for equity markets, the Exchange believed it would, indirectly, potentially impact the options markets as well. Thus, the Exchange has previously adopted and amended Rule IM–7170–1 to ensure the option markets were not harmed as a result of the Plan's implementation and implemented the rule on a pilot basis that has coincided with the pilot period for the Plan (''Options Pilot'').[6]

Rule IM–7170–1 provides that transactions executed during a limit or straddle state are not subject to the obvious and catastrophic error rules. A limit or straddle state occurs when at least one side of the National Best Bid (''NBB'') or Offer (''NBO'') bid/ask is priced at a non-tradable level. Specifically, a straddle state exists when the NBB is below the lower price band while the NBO is inside the prices band or when the NBO is above the upper price band and the NBB is within the band, while a limit state occurs when the NBO equals the lower price band (without crossing the NBB), or the NBB equals the upper price band (without crossing the NBO). The Exchange adopted the Options Pilot to protect investors because when an underlying security is in a limit or straddle state, there will not be a reliable price for the security to serve as a benchmark for the price of the option. Specifically, the Exchange adopted Rule IM–7170–1 because the application of the obvious and catastrophic error rules would be impracticable given the potential for lack of a reliable NBBO in the options market during limit and straddle states. When adjusting or busting a trade pursuant to the obvious error rule, the determination of theoretical value of a trade generally references the NBB (for erroneous sell transactions) or NBO (for erroneous buy transactions) just prior to the trade in question, and is therefore not reliable when at least one side of the NBBO is priced at a non-tradeable level, as is the case in limit and straddle states. In such a situation, determining theoretical value may often times be a very subjective rather than an objective determination and could give rise to additional uncertainty and confusion for investors. As a result, application of the obvious and catastrophic error rules would be impracticable given the lack of a reliable NBBO in the options market during limit and straddle states, and may produce undesirable effects or unanticipated consequences. The Exchange adopted IM–7170–1 as an additional measure designed to protect investors during limit and straddle states. For example, the Exchange believes that eliminating the application of obvious error rules during a limit or straddle state eliminates the re-evaluation of a transaction executed during such a state that could potentially create an unreasonable adverse selection opportunity due to lack of a reliable reference price on one side of the market or another and discourage participants from providing liquidity during limit and straddle states, which is contrary to the goal in limiting participants' adverse selection with the application of the obvious error rule during normal trading states. The Exchange believes the Options Pilot is designed to add certainty on the options markets, which encourages more investors to participate in light of the changes associated with the Plan. The Plan was originally implemented on a pilot-basis in order to allow the public, the participating exchanges, and the Commission to assess the operation of the Plan and whether the Plan should be modified prior to approval on a permanent basis. As stated, the Exchange adopted the Option Pilot to coincide with this pilot; to continue the protections therein while the industry gains further experience operating the Plan.

In connection with the order approving the establishment of the obvious error pilot, as well as the extensions of the obvious error pilot, the Exchange committed to submit monthly data regarding the program and to submit an overall analysis of the obvious error pilot in conjunction with the data submitted under the Plan and any other data as requested by the Commission. Pursuant to a rule filing, approved on May 8, 2015, each month, the Exchange committed to provide the Commission, and the public, a dataset containing the data for each straddle and limit state in optionable stocks that had at least one trade on the Exchange.[7] The Exchange has continued to provide the Commission with this data on a monthly basis from May 2015. For each trade on the Exchange, the Exchange provides (a) the stock symbol, option symbol, time at the start of the straddle or limit state, an indicator for whether it is a straddle or limit state, and (b) for the trades on the Exchange, the executed volume, time-weighted quoted bid-ask spread, time-weighted average quoted depth at the bid, time-weighted average quoted depth at the offer, high execution price, low execution price, number of trades for which a request for review for error was received during straddle and limit states, an indicator variable for whether those options outlined above have a price change

[3] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (Order Approving Amendment No. 18).

[4] *See* Securities Exchange Act Release No. 64547 (May 25, 2011), 76 FR 31647 (June 1, 2011) (File No. 4–631).

[5] *See* Securities and Exchange Act Release No. 67091 (May 31, 2012) 77 FR 33498 (June 6, 2012).

[6] *See* Securities Exchange Act Release Nos. 34–76233 (October 22, 2015), 80 FR 66087 (October 28, 2015) (SR–BOX–2015–34) (proposing to extend pilot program to coincide with the pilot period for the Plan).

[7] *See* Securities Exchange Act Release No. 34–74911 (May 8, 2015), 80 FR 27717 (May 14, 2019) (SR–BOX–2015–18); *see also* BOX Limit Up Limit Down Reports *https://boxoptions.com/regulatory/governing-documents-related-information-nms-plans/pilot-reports/limit-up-down/.*

exceeding 30% during the underlying stock's limit or straddle state compared to the last available option price as reported by OPRA before the start of the limit or straddle state. In addition, to help evaluate the impact of the pilot program, the Exchange has provided to the Commission assessments evaluating the options market quality during Limit and Straddle States, the character of incoming order flow and transactions during Limit and Straddle States, and reviews of any complaints from members and their customers concerning executions during Limit and Straddle States. The Exchange has concluded that the obvious error pilot does not negatively impact market quality during normal market conditions, and that there has been insufficient data to assess whether a lack of obvious error rules is problematic, however, the Exchange believes the continuation of Rule IM–7170–1 functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets.

The Commission recently approved the Plan on a permanent basis (Amendment 18).[8] In connection with this approval, the Exchange now proposes to amend the Exchange Rule IM–7170–1 that currently implement the provisions of the Plan on a pilot basis to eliminate the pilot basis, which effectiveness expires on October 18, 2019, and to make such rules permanent. In its approval order to make the Plan permanent, the Commission recognized that, as a result of the Participants' and industry analysis of the Plan's operation, the Limit Up-Limit Down mechanism effectively addresses extraordinary market volatility. Indeed, the Plan benefits markets and market participants by helping to ensure orderly markets, but also, the Exchange believes, based on the data made available to the public and the Commission during the pilot period, that the obvious error pilot does not negatively impact market quality during normal market conditions. Rather, the Exchange believes the obvious error pilot functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. This removes impediments to and perfects the mechanism of a free and open market and national market system by encouraging more investors to participate in light of the changes associated with the Plan. The Exchange believes that if approved on a permanent basis, the Options Pilot would permanently provide investors with the above-described additional certainty of market prices and mitigation of unanticipated consequences and unreasonable adverse selection risk during limit and straddle states.

The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs. Since the Commission's approval of Amendment 18 allowing the Plan to operate on a permanent basis, the Exchange and other national securities exchanges have determined that no further amendments should be made to the Options Pilot; the current Option Pilot effectively addresses extraordinary market volatility, is reasonably designed to comply with the requirements of the Plan, facilitates compliance with the Plan and should now operate on a permanent basis, consistent with the Plan. The Exchange does not propose any substantive or additional changes to Exchange Rule IM–7170–1.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[9] in general, and Section 6(b)(5) of the Act,[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [11] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, The Exchange believes that the proposed rule supports the objectives of perfecting the mechanism of a free and open market and the national market system because it promotes transparency and uniformity across markets concerning rules for options markets adopted to coincide with the Plan. The Exchange believes that eliminating the pilot basis for the Options Pilot and making the rule permanent facilitates compliance with the Plan by adding certainty to the markets during periods of market volatility, which has been approved and found by the Commission to be reasonably designed to prevent potentially harmful price volatility in NMS Stocks. It has been determined by the Commission that the Plan benefits markets and market participants by helping to ensure orderly markets, and, based on the data made available to the public and the Commission during the pilot period for Rule IM–7170–1, the Plan does not negatively impact options market quality during normal market conditions. Rather, the Plan, as it is implemented under the obvious error pilot, functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and adds certainty on the options markets. During a limit or straddle state, determining theoretical value of an option may be a subjective rather than an objective determination given the lack of a reliable NBBO, which may create an unreasonable adverse selection opportunity and discourage participants from providing liquidity during limit and straddle states. Therefore, the Exchange believes eliminating obvious error review in such states would, in turn, eliminate uncertainty and confusion for investors and benefit investors by encouraging more participation in light of the changes associated with the Plan.

Accordingly, the Exchange believes that making the Options Pilot permanent will further the goals of investor protection and fair and orderly markets as the rule effectively addresses extraordinary market volatility pursuant to the Plan.

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. In this regard and as indicated above, this change is being proposed in connection with the recently approved amendment to the Limit Up-Limit Down Plan that allows the Plan to continue to operate on a permanent basis.[12] The proposed rule change is necessary to reflect that the Plan no longer operates as a pilot and has been approved to operate on a permanent basis by the Commission. As such, Exchange Rule IM–7170–1, which implements protections in connection

[8] *See supra* note 3.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Id.*

[12] *See supra,* note 3.

with the Plan, should be amended to operate on a permanent basis. The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

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 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)(3)(A)(iii) of the Act [13] and subparagraph (f)(6) of Rule 19b–4 thereunder.[14]

A proposed rule change filed under Rule 19b–4(f)(6) [15] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [16] 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 proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current Options Pilots to continue on a permanent basis without any changes, prior to the pilot expiration on October 18, 2019. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[17]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2019–31 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–BOX–2019–31. 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–BOX–2019–31 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Eduardo A. Aleman,

Deputy Secretary.

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[13] 15 U.S.C. 78s(b)(3)(A)(iii).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6)(iii).

[17] 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).

[18] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87368; File No. SR–BX–2019–038]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make Permanent Certain Options Market Rules That Are Linked to the Equity Market Plan To Address Extraordinary Market Volatility

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2019, Nasdaq BX, Inc. (''BX'' 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 make permanent certain options market rules that are linked to the equity market Plan to Address Extraordinary Market Volatility.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.com/,* at

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to make permanent certain options market rules in connection with the equity market Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or the ''Plan''). This change is being proposed in connection with the recently approved amendment to the Limit Up-Limit Down Plan that allows the Plan to continue to operate on a permanent basis (''Amendment 18'').[3] This proposed rule change is substantially similar to a recently-approved rule change by Cboe Exchange, Inc. (''Cboe'').[4]

In an attempt to address extraordinary market volatility in NMS Stocks, and, in particular, events like the severe volatility on May 6, 2010, U.S. national securities exchanges and the Financial Industry Regulatory Authority, Inc. (collectively, ''Participants'') drafted the Plan pursuant to Rule 608 of Regulation NMS and under the Act.[5] On May 31, 2012, the Commission approved the Plan, as amended, on a one-year pilot basis.[6] Though the Plan was primarily designed for equity markets, the Exchange believed it would, indirectly, potentially impact the options markets as well. Thus, the Exchange has previously adopted and amended Chapter V, Section 3(d) to ensure the option markets were not harmed as a result of the Plan's implementation and has implemented such rules on a pilot basis that has coincided with the pilot period for the Plan (the ''Options Pilots'').[7] Chapter V, Section 3(d) addresses the interplay of the Exchange's rules in response to the Plan, and includes provisions on how the Exchange will treat certain options orders during a limit or straddle state as well as options market maker quoting obligations during a limit or straddle state. In addition, Section 3(d)(iv) provides that during a limit or straddle state, trades are not subject to obvious or catastrophic error review. A limit or straddle state occurs when at least one side of the National Best Bid (''NBB'') or Offer (''NBO'') bid/ask is priced at a non-tradable level. Specifically, a straddle state exists when the NBB is below the lower price band while the NBO is inside the prices band or when the NBO is above the upper price band and the NBB is within the band, while a limit state occurs when the NBO equals the lower price band (without crossing the NBB), or the NBB equals the upper price band (without crossing the NBO). The Exchange adopted the Options Pilots to protect investors because when an underlying security is in a limit up-limit down state, there will not be a reliable price for the security to serve as a benchmark for the price of the option. Specifically, the Exchange adopted Chapter V, Section 3(d)(iv) because the application of the obvious and catastrophic error rules would be impracticable given the potential for lack of a reliable NBBO in the options market during limit and straddle states. When adjusting or busting a trade pursuant to the obvious error rule, the determination of theoretical value of a trade generally references the NBB (for erroneous sell transactions) or NBO (for erroneous buy transactions) just prior to the trade in question, and is therefore not reliable when at least one side of the NBBO is priced at a non-tradeable level, as is the case in limit and straddle states. In such a situation, determining theoretical value may often times be a very subjective rather than an objective determination and could give rise to additional uncertainty and confusion for investors. As a result, application of the obvious and catastrophic error rules would be impracticable given the lack of a reliable NBBO in the options market during limit and straddle states, and may produce undesirable effects or unanticipated consequences. As noted above, the Exchange adopted additional measures via other Options Pilot rules that are designed to protect investors during limit and straddle states.[8] For example, the Exchange will reject Market Orders (as defined in Chapter VI, Section 1) during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state. Furthermore, the Exchange believes that eliminating the application of obvious error rules during a limit or straddle state eliminates the re-evaluation of a transaction executed during such a state that could potentially create an unreasonable adverse selection opportunity due to the lack of a reliable reference price on one side of the market or another and discourage participants from providing liquidity during limit and straddle states, which is contrary to the goal in limiting participants' adverse selection with the application of the obvious error rule during normal trading states. For these reasons, the Exchange believes the Options Pilots and related rules are designed to add certainty on the options markets, which encourages more investors to participate in light of the changes associated with the Plan. The Plan was originally implemented on a pilot-basis in order to allow the public, the participating exchanges, and the Commission to assess the operation of the Plan and whether the Plan should be modified prior to approval on a permanent basis. As stated, the Exchange adopted the Option Pilots to coincide with this pilot; to continue the protections therein while the industry gains further experience operating the Plan.

In connection with the order approving the establishment of the obvious error pilot, as well as the extensions of the obvious error pilot, the Exchange committed to submit monthly data regarding the program and to submit an overall analysis of the obvious error pilot in conjunction with

[3] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (Order Approving Amendment No. 18).

[4] *See* Securities Exchange Act Release Nos. 86744 (August 23, 2019), 84 FR 45565 (August 29, 2019) (SR–CBOE–2019–049) (Notice of Filing); and 87311 (October 15, 2019) (SR–CBOE–2019–049) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2). The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.

[5] *See* Securities Exchange Act Release No. 64547 (May 25, 2011), 76 FR 31647 (June 1, 2011) (File No. 4–631).

[6] *See* Securities and Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012).

[7] *See* Securities Exchange Act Release Nos. 69119 (March 12, 2013), 78 FR 16746 (March 18, 2013) (SR–BX–2013–021); 69334 (April 5, 2013), 78 FR 21653 (April 11, 2013) (SR–BX–2013–022); and 69343 (April 8, 2013), 78 FR 21982 (April 12, 2013) (SR–BX–2013–026).

[8] As set forth in Chapter V, Section 3(d), this includes rules in connection with special handling for Market Orders, and options market maker quoting obligations during a limit or straddle state.

the data submitted under the Plan and any other data as requested by the Commission. Pursuant to a rule filing, approved on April 8, 2014, each month, the Exchange committed to provide the Commission, and the public, a dataset containing the data for each straddle and limit state in optionable stocks that had at least one trade on the Exchange.[9] The Exchange has continued to provide the Commission with this data on a monthly basis. For each trade on the Exchange, the Exchange provides (a) the stock symbol, option symbol, time at the start of the straddle or limit state, an indicator for whether it is a straddle or limit state, and (b) for the trades on the Exchange, the executed volume, time-weighted quoted bid-ask spread, time-weighted average quoted depth at the bid, time-weighted average quoted depth at the offer, high execution price, low execution price, number of trades for which a request for review for error was received during straddle and limit states, an indicator variable for whether those options outlined above have a price change exceeding 30% during the underlying stock's limit or straddle state compared to the last available option price as reported by OPRA before the start of the limit or straddle state. In addition, to help evaluate the impact of the pilot program, the Exchange has provided to the Commission, and the public, assessments relating to the impact of the operation of the obvious error rules during limit and straddle states including: (1) An evaluation of the statistical and economic impact of limit and straddle states on liquidity and market quality in the options markets, and (2) an assessment of whether the lack of obvious error rules in effect during the straddle and limit states are problematic. The Exchange has concluded that the Options Pilots do not negatively impact market quality during normal market conditions,[10] and that there has been insufficient data to assess whether a lack of obvious error rules is problematic, however, the Exchange believes the continuation of the Options Pilots function to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets.

The Commission recently approved the Plan on a permanent basis (Amendment 18).[11] In connection with this approval, the Exchange now proposes to amend Chapter V, Section 3(d) that currently implement provisions of the Plan on a pilot basis to eliminate the pilot basis, which effectiveness expires on October 18, 2019, and to make such rules permanent. In its approval order to make the Plan permanent, the Commission recognized that, as a result of the Participants' and industry analysis of the Plan's operation, the Limit Up-Limit Down mechanism effectively addresses extraordinary market volatility. Indeed, the Plan benefits markets and market participants by helping to ensure orderly markets, but also, the Exchange believes, based on the data made available to the public and the Commission during the pilot period, that the obvious error pilot does not negatively impact market quality during normal market conditions.[12] Rather, the Exchange believes the obvious error pilot functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. The Exchange also believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[13] This removes impediments to and perfects the mechanism of a free and open market and national market system by encouraging more investors to participate in light of the changes associated with the Plan. The Exchange believes that if approved on a permanent basis, the Options Pilots would permanently provide investors with the above-described additional certainty of market prices and mitigation of unanticipated consequences and unreasonable adverse selection risk during limit and straddle states.

Since the Commission's approval of Amendment 18 allowing the Plan to operate on a permanent basis, the Exchange and other national securities exchanges have determined that no further amendments should be made to the Options Pilots;[14] the current Options Pilots effectively address extraordinary market volatility, are reasonably designed to comply with the requirements of the Plan, facilitate compliance with the Plan and should now operate on a permanent basis, consistent with the Plan. The Exchange does not propose any substantive or additional changes to Chapter V, Section 3(d).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[15] in general, and Section 6(b)(5) of the Act,[16] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed rule supports the objectives of perfecting the mechanism of a free and open market and the national market system because it promotes transparency and uniformity across markets concerning rules for options markets adopted to coincide with the Plan. The Exchange believes that eliminating the pilot basis for the Options Pilots and making such rules permanent facilitates compliance with the Plan by adding certainty to the markets during periods of market volatility, which has been approved and found by the Commission to be reasonably designed to prevent potentially harmful price volatility in NMS Stocks. It has been determined by the Commission that the Plan benefits markets and market participants by helping to ensure orderly markets, and, based on the data made available to the public and the Commission during the pilot period for Chapter V, Section 3(d)(iv), the Plan does not negatively impact options market quality during normal market conditions. Rather, the Plan, as it is implemented under the obvious error pilot, functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. During a limit or

[9] *See* Securities Exchange Act Release No. 71900 (April 8, 2014), 79 FR 20951 (April 14, 2014) (SR–BX–2014–017); *see also* BX LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.*

[10] *See also* BX LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.* During the most recent Review Period the Exchange did not receive any obvious error review requests for Limit-Up-Limit Down trades, and Limit Up-Limit Down trade volume accounted for nominal overall trade volume.

[11] *See supra* note 3.

[12] *See supra* note 10.

[13] *See supra* note 8.

[14] *See* Securities Exchange Act Release No. 85622 (April 11, 2019), 84 FR 16116 (April 17, 2019) (SR–BX–2019–007).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

straddle state, determining theoretical value of an option may be a subjective rather than an objective determination given the lack of a reliable NBBO, which may create an unreasonable adverse selection opportunity and discourage participants from providing liquidity during limit and straddle states. Therefore, the Exchange believes eliminating obvious error review in such states would, in turn, eliminate uncertainty and confusion for investors and benefit investors by encouraging more participation in light of the changes associated with the Plan. As stated, the Exchange believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[17] Accordingly, the Exchange believes that making the Options Pilots permanent will further the goals of investor protection and fair and orderly markets as the rules effectively address extraordinary market volatility pursuant to the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is necessary to reflect that the Plan no longer operates as a pilot and has been approved to operate on a permanent basis by the Commission. As such, Chapter V, Section 3(d), which implement protections in connection with the Plan, should be amended to operate on a permanent basis. The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.[18] Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

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.

[17] *See supra* note 8.

[18] In addition, the Exchange's proposal is substantially similar to Cboe's recently approved rule change. *See supra* note 4.

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 under Rule 19b–4(f)(6) [21] normally does not become operative prior to 30 days after the date of the 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 asked the Commission to waive the 30-day operative delay so that the proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current Options Pilots to continue on a permanent basis without any changes, prior to the pilot expiration on October 18, 2019. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as 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.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[21] 17 CFR 240.19b–4(f)(6).

[22] 17 CFR 240.19b–4(f)(6)(iii).

[23] 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).

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–BX–2019–038 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–BX–2019–038. 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–BX–2019–038 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–23254 Filed 10–24–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87370; File No. SR–NASDAQ–2019–086]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make Permanent Certain Options Market Rules That Are Linked to the Equity Market Plan To Address Extraordinary Market Volatility

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2019, The Nasdaq Stock Market LLC (''Nasdaq'' 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 make permanent certain options market rules that are linked to the equity market Plan to Address Extraordinary Market Volatility.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.cchwallstreet.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to make permanent certain options market rules in connection with the equity market Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or the ''Plan''). This change is being proposed in connection with the recently approved amendment to the Limit Up-Limit Down Plan that allows the Plan to continue to operate on a permanent basis (''Amendment 18'').[3] This proposed rule change is substantially similar to a recently-approved rule change by Cboe Exchange, Inc. (''Cboe'').[4]

In an attempt to address extraordinary market volatility in NMS Stocks, and, in particular, events like the severe volatility on May 6, 2010, U.S. national securities exchanges and the Financial Industry Regulatory Authority, Inc. (collectively, ''Participants'') drafted the Plan pursuant to Rule 608 of Regulation NMS and under the Act.[5] On May 31, 2012, the Commission approved the Plan, as amended, on a one-year pilot basis.[6] Though the Plan was primarily designed for equity markets, the Exchange believed it would, indirectly, potentially impact the options markets as well. Thus, the Exchange has previously adopted and amended Chapter V, Section 3(d) to ensure the option markets were not harmed as a result of the Plan's implementation and has implemented such rules on a pilot basis that has coincided with the pilot period for the Plan (the ''Options Pilots'').[7] Chapter V, Section 3(d) addresses the interplay of the Exchange's rules in response to the Plan, and includes provisions on how the Exchange will treat certain options orders during a limit or straddle state as well as options market maker quoting obligations during a limit or straddle state. In addition, Section 3(d)(iv) provides that during a limit or straddle state, trades are not subject to obvious or catastrophic error review. A limit or straddle state occurs when at least one side of the National Best Bid (''NBB'') or Offer (''NBO'') bid/ask is priced at a non-tradable level. Specifically, a straddle state exists when the NBB is below the lower price band while the NBO is inside the prices band or when the NBO is above the upper price band and the NBB is within the band, while a limit state occurs when the NBO equals the lower price band (without crossing the NBB), or the NBB equals the upper price band (without crossing the NBO). The Exchange adopted the Options Pilots to protect investors because when an underlying security is in a limit up-limit down state, there will not be a reliable price for the security to serve as a benchmark for the price of the option. Specifically, the Exchange adopted Chapter V, Section 3(d)(iv) because the application of the obvious and catastrophic error rules would be impracticable given the potential for lack of a reliable NBBO in the options market during limit and straddle states. When adjusting or busting a trade pursuant to the obvious error rule, the determination of theoretical value of a trade generally references the NBB (for erroneous sell transactions) or NBO (for erroneous buy transactions) just prior to the trade in question, and is therefore not reliable when at least one side of the NBBO is priced at a non-tradeable level, as is the case in limit and straddle states. In such a situation, determining theoretical value may often times be a very subjective rather than an objective determination and could give rise to additional uncertainty and confusion for investors. As a result, application of the obvious and catastrophic error rules would be impracticable given the lack of a reliable NBBO in the options market during limit and straddle states, and may produce undesirable effects or unanticipated consequences. As noted above, the Exchange adopted additional measures via other Options Pilot rules that are designed to protect investors

[24] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (Order Approving Amendment No. 18).

[4] *See* Securities Exchange Act Release Nos. 86744 (August 23, 2019), 84 FR 45565 (August 29, 2019) (SR–CBOE–2019–049) (Notice of Filing); and 87311 (October 15, 2019) (SR–CBOE–2019–049) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2). The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.

[5] *See* Securities Exchange Act Release No. 64547 (May 25, 2011), 76 FR 31647 (June 1, 2011) (File No. 4–631).

[6] *See* Securities and Exchange Act Release No. 67091 (May 31, 2012) 77 FR 33498 (June 6, 2012).

[7] *See* Securities Exchange Act Release Nos. 69120 (March 12, 2013), 78 FR 16740 (March 18, 2013) (SR–NASDAQ–2013–040); 69333 (April 5, 2013), 78 FR 21675 (April 11, 2013) (SR–NASDAQ–2013–043); and 69341 (April 8, 2013), 78 FR 21996 (April 12, 2013) (SR–NASDAQ–2013–048).

during limit and straddle states.[8] For example, the Exchange will reject Market Orders (as defined in Chapter VI, Section 1) during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state. Furthermore, the Exchange believes that eliminating the application of obvious error rules during a limit or straddle state eliminates the re-evaluation of a transaction executed during such a state that could potentially create an unreasonable adverse selection opportunity due to the lack of a reliable reference price on one side of the market or another and discourage participants from providing liquidity during limit and straddle states, which is contrary to the goal in limiting participants' adverse selection with the application of the obvious error rule during normal trading states. For these reasons, the Exchange believes the Options Pilots and related rules are designed to add certainty on the options markets, which encourages more investors to participate in light of the changes associated with the Plan. The Plan was originally implemented on a pilot-basis in order to allow the public, the participating exchanges, and the Commission to assess the operation of the Plan and whether the Plan should be modified prior to approval on a permanent basis. As stated, the Exchange adopted the Option Pilots to coincide with this pilot; to continue the protections therein while the industry gains further experience operating the Plan.

In connection with the order approving the establishment of the obvious error pilot, as well as the extensions of the obvious error pilot, the Exchange committed to submit monthly data regarding the program and to submit an overall analysis of the obvious error pilot in conjunction with the data submitted under the Plan and any other data as requested by the Commission. Pursuant to a rule filing, approved on April 8, 2014, each month, the Exchange committed to provide the Commission, and the public, a dataset containing the data for each straddle and limit state in optionable stocks that had at least one trade on the Exchange.[9] The Exchange has continued to provide the Commission with this data on a monthly basis. For each trade on the Exchange, the Exchange provides (a) the stock symbol, option symbol, time at the start of the straddle or limit state, an indicator for whether it is a straddle or limit state, and (b) for the trades on the Exchange, the executed volume, time-weighted quoted bid-ask spread, time-weighted average quoted depth at the bid, time-weighted average quoted depth at the offer, high execution price, low execution price, number of trades for which a request for review for error was received during straddle and limit states, an indicator variable for whether those options outlined above have a price change exceeding 30% during the underlying stock's limit or straddle state compared to the last available option price as reported by OPRA before the start of the limit or straddle state. In addition, to help evaluate the impact of the pilot program, the Exchange has provided to the Commission, and the public, assessments relating to the impact of the operation of the obvious error rules during limit and straddle states including: (1) An evaluation of the statistical and economic impact of limit and straddle states on liquidity and market quality in the options markets, and (2) an assessment of whether the lack of obvious error rules in effect during the straddle and limit states are problematic. The Exchange has concluded that the Options Pilots do not negatively impact market quality during normal market conditions,[10] and that there has been insufficient data to assess whether a lack of obvious error rules is problematic, however, the Exchange believes the continuation of the Options Pilots function to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets.

The Commission recently approved the Plan on a permanent basis (Amendment 18).[11] In connection with this approval, the Exchange now proposes to amend Chapter V, Section 3(d) that currently implement provisions of the Plan on a pilot basis to eliminate the pilot basis, which effectiveness expires on October 18, 2019, and to make such rules permanent. In its approval order to make the Plan permanent, the Commission recognized that, as a result of the Participants' and industry analysis of the Plan's operation, the Limit Up-Limit Down mechanism effectively addresses extraordinary market volatility. Indeed, the Plan benefits markets and market participants by helping to ensure orderly markets, but also, the Exchange believes, based on the data made available to the public and the Commission during the pilot period, that the obvious error pilot does not negatively impact market quality during normal market conditions.[12] Rather, the Exchange believes the obvious error pilot functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. The Exchange also believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[13] This removes impediments to and perfects the mechanism of a free and open market and national market system by encouraging more investors to participate in light of the changes associated with the Plan. The Exchange believes that if approved on a permanent basis, the Options Pilots would permanently provide investors with the above-described additional certainty of market prices and mitigation of unanticipated consequences and unreasonable adverse selection risk during limit and straddle states.

Since the Commission's approval of Amendment 18 allowing the Plan to operate on a permanent basis, the Exchange and other national securities exchanges have determined that no further amendments should be made to the Options Pilots;[14] the current Options Pilots effectively address extraordinary market volatility, are reasonably designed to comply with the requirements of the Plan, facilitate compliance with the Plan and should now operate on a permanent basis, consistent with the Plan. The Exchange does not propose any substantive or

[8] As set forth in Chapter V, Section 3(d), this includes rules in connection with special handling for Market Orders, and options market maker quoting obligations during a limit or straddle state.

[9] *See* Securities Exchange Act Release No. 71902 (April 8, 2014), 79 FR 20946 (April 14, 2014) (SR–NASDAQ–2014–033); *see also* Nasdaq LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.*

[10] *See also* Nasdaq LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.* During the most recent Review Period the Exchange did not receive any obvious error review requests for Limit-Up-Limit Down trades, and Limit Up-Limit Down trade volume accounted for nominal overall trade volume.

[11] *See supra* note 3.

[12] *See supra* note 10.

[13] *See supra* note 8.

[14] *See* Securities Exchange Act Release No. 85631 (April 11, 2019), 84 FR 16100 (April 17, 2019) (SR–NASDAQ–2019–026).

additional changes to Chapter V, Section 3(d).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[15] in general, and Section 6(b)(5) of the Act,[16] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed rule supports the objectives of perfecting the mechanism of a free and open market and the national market system because it promotes transparency and uniformity across markets concerning rules for options markets adopted to coincide with the Plan. The Exchange believes that eliminating the pilot basis for the Options Pilots and making such rules permanent facilitates compliance with the Plan by adding certainty to the markets during periods of market volatility, which has been approved and found by the Commission to be reasonably designed to prevent potentially harmful price volatility in NMS Stocks. It has been determined by the Commission that the Plan benefits markets and market participants by helping to ensure orderly markets, and, based on the data made available to the public and the Commission during the pilot period for Chapter V, Section 3(d)(iv), the Plan does not negatively impact options market quality during normal market conditions. Rather, the Plan, as it is implemented under the obvious error pilot, functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. During a limit or straddle state, determining theoretical value of an option may be a subjective rather than an objective determination given the lack of a reliable NBBO, which may create an unreasonable adverse selection opportunity and discourage participants from providing liquidity during limit and straddle states. Therefore, the Exchange believes eliminating obvious error review in such states would, in turn, eliminate uncertainty and confusion for investors and benefit investors by encouraging more participation in light of the changes associated with the Plan. As stated, the Exchange believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[17] Accordingly, the Exchange believes that making the Options Pilots permanent will further the goals of investor protection and fair and orderly markets as the rules effectively address extraordinary market volatility pursuant to the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is necessary to reflect that the Plan no longer operates as a pilot and has been approved to operate on a permanent basis by the Commission. As such, Chapter V, Section 3(d), which implement protections in connection with the Plan, should be amended to operate on a permanent basis. The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.[18] Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

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 under Rule 19b–4(f)(6)[21] normally does not become operative prior to 30 days after the date of the 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 asked the Commission to waive the 30-day operative delay so that the proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current Options Pilots to continue on a permanent basis without any changes, prior to the pilot expiration on October 18, 2019. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as 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:

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] *See supra* note 8.

[18] In addition, the Exchange's proposal is substantially similar to Cboe's recently approved rule change. *See supra* note 4.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[21] 17 CFR 240.19b–4(f)(6).

[22] 17 CFR 240.19b–4(f)(6)(iii).

[23] 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).

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2019–086 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–NASDAQ–2019–086. 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–NASDAQ–2019–086 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–23256 Filed 10–24–19; 8:45 am]

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[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87371; File No. SR–GEMX–2019–16]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make Permanent Certain Options Market Rules That Are Linked to the Equity Market Plan To Address Extraordinary Market Volatility

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2019, 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 make permanent certain options market rules that are linked to the equity market Plan to Address Extraordinary Market Volatility.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqgemx.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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to make permanent certain options market rules in connection with the equity market Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or the ''Plan''). This change is being proposed in connection with the recently approved amendment to the Limit Up-Limit Down Plan that allows the Plan to continue to operate on a permanent basis (''Amendment 18'').[3] This proposed rule change is substantially similar to a recently-approved rule change by Cboe Exchange, Inc. (''Cboe'').[4]

In an attempt to address extraordinary market volatility in NMS Stocks, and, in particular, events like the severe volatility on May 6, 2010, U.S. national securities exchanges and the Financial Industry Regulatory Authority, Inc. (collectively, ''Participants'') drafted the Plan pursuant to Rule 608 of Regulation NMS and under the Act.[5] On May 31, 2012, the Commission approved the Plan, as amended, on a one-year pilot basis.[6] Though the Plan was primarily designed for equity markets, the Exchange believed it would, indirectly, potentially impact the options markets as well. Thus, the Exchange has previously adopted and amended Options 3, Section 9(d) and Supplementary Material .01 to Options 3, Section 20 to ensure the option markets were not harmed as a result of the Plan's implementation and has implemented such rules on a pilot basis that has coincided with the pilot period for the Plan (the ''Options Pilots'').[7] Options 3, Section 9(d) addresses the

[3] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (Order Approving Amendment No. 18).

[4] *See* Securities Exchange Act Release Nos. 86744 (August 23, 2019), 84 FR 45565 (August 29, 2019) (SR–CBOE–2019–049) (Notice of Filing); and 87311 (October 15, 2019) (SR–CBOE–2019–049) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2). The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.

[5] *See* Securities Exchange Act Release No. 64547 (May 25, 2011), 76 FR 31647 (June 1, 2011) (File No. 4–631).

[6] *See* Securities and Exchange Act Release No. 67091 (May 31, 2012) 77 FR 33498 (June 6, 2012).

[7] *See* Securities Exchange Act Release Nos. 74897 (May 7, 2015), 80 FR 27415 (May 13, 2015) (SR–ISEGemini–2015–11) (''Original Obvious Error Proposal''); and 80011 (February 10, 2017), 82 FR 10927 (February 16, 2017) (SR–ISEGemini–2016–17).

interplay of the Exchange's rules in response to the Plan, and includes provisions on how the Exchange will treat certain options orders during a limit or straddle state as well as options market maker quoting obligations during a limit or straddle state. In addition, Supplementary Material .01 to Options 3, Section 20 provides that an execution will not be subject to obvious or catastrophic error review if it occurred during a limit or straddle state. A limit or straddle state occurs when at least one side of the National Best Bid (''NBB'') or Offer (''NBO'') bid/ask is priced at a non-tradable level. Specifically, a straddle state exists when the NBB is below the lower price band while the NBO is inside the prices band or when the NBO is above the upper price band and the NBB is within the band, while a limit state occurs when the NBO equals the lower price band (without crossing the NBB), or the NBB equals the upper price band (without crossing the NBO). The Exchange adopted the Options Pilots to protect investors because when an underlying security is in a limit up-limit down state, there will not be a reliable price for the security to serve as a benchmark for the price of the option. Specifically, the Exchange adopted Supplementary Material .01 to Options 3, Section 20 because the application of the obvious and catastrophic error rules would be impracticable given the potential for lack of a reliable NBBO in the options market during limit and straddle states. When adjusting or busting a trade pursuant to the obvious error rule, the determination of theoretical value of a trade generally references the NBB (for erroneous sell transactions) or NBO (for erroneous buy transactions) just prior to the trade in question, and is therefore not reliable when at least one side of the NBBO is priced at a non-tradeable level, as is the case in limit and straddle states. In such a situation, determining theoretical value may often times be a very subjective rather than an objective determination and could give rise to additional uncertainty and confusion for investors. As a result, application of the obvious and catastrophic error rules would be impracticable given the lack of a reliable NBBO in the options market during limit and straddle states, and may produce undesirable effects or unanticipated consequences. As noted above, the Exchange adopted additional measures via other Options Pilot rules that are designed to protect investors during limit and straddle states.[8] For example, the Exchange will reject Market Orders (as defined in Options 3, Section 7(a)) and cancel Stop Orders [9] during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state. Furthermore, the Exchange believes that eliminating the application of obvious error rules during a limit or straddle state eliminates the re-evaluation of a transaction executed during such a state that could potentially create an unreasonable adverse selection opportunity due to the lack of a reliable reference price on one side of the market or another and discourage participants from providing liquidity during limit and straddle states, which is contrary to the goal in limiting participants' adverse selection with the application of the obvious error rule during normal trading states. For these reasons, the Exchange believes the Options Pilots and related rules are designed to add certainty on the options markets, which encourages more investors to participate in light of the changes associated with the Plan. The Plan was originally implemented on a pilot-basis in order to allow the public, the participating exchanges, and the Commission to assess the operation of the Plan and whether the Plan should be modified prior to approval on a permanent basis. As stated, the Exchange adopted the Option Pilots to coincide with this pilot; to continue the protections therein while the industry gains further experience operating the Plan.

In connection with the order approving the establishment of the obvious error pilot, as well as the extensions of the obvious error pilot, the Exchange committed to submit monthly data regarding the program and to submit an overall analysis of the obvious error pilot in conjunction with the data submitted under the Plan and any other data as requested by the Commission. Pursuant to the Original Obvious Error Proposal, approved on May 7, 2015, each month, the Exchange committed to provide the Commission, and the public, a dataset containing the data for each straddle and limit state in optionable stocks that had at least one trade on the Exchange.[10] The Exchange has continued to provide the Commission with this data on a monthly basis. For each trade on the Exchange, the Exchange provides (a) the stock symbol, option symbol, time at the start of the straddle or limit state, an indicator for whether it is a straddle or limit state, and (b) for the trades on the Exchange, the executed volume, time-weighted quoted bid-ask spread, time-weighted average quoted depth at the bid, time-weighted average quoted depth at the offer, high execution price, low execution price, number of trades for which a request for review for error was received during straddle and limit states, an indicator variable for whether those options outlined above have a price change exceeding 30% during the underlying stock's limit or straddle state compared to the last available option price as reported by OPRA before the start of the limit or straddle state. In addition, to help evaluate the impact of the pilot program, the Exchange has provided to the Commission, and the public, assessments relating to the impact of the operation of the obvious error rules during limit and straddle states including: (1) An evaluation of the statistical and economic impact of limit and straddle states on liquidity and market quality in the options markets, and (2) an assessment of whether the lack of obvious error rules in effect during the straddle and limit states are problematic. The Exchange has concluded that the Options Pilots do not negatively impact market quality during normal market conditions,[11] and that there has been insufficient data to assess whether a lack of obvious error rules is problematic, however, the Exchange believes the continuation of the Options Pilots function to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets.

The Commission recently approved the Plan on a permanent basis (Amendment 18).[12] In connection with this approval, the Exchange now proposes to amend Options 3, Section 9(d) and Supplementary Material .01 to Options 3, Section 20 that currently implement provisions of the Plan on a pilot basis to eliminate the pilot basis,

[8] As set forth in Options 3, Section 9(d), this includes rules in connection with special handling for Market Orders and Stop Orders, and options market maker quoting obligations during a limit or straddle state.

[9] The Exchange will elect Stop Orders if the condition as provided in Options 3, Section 7(d) is met, and, because they become Market Orders, will then cancel them back. *See* Options 3, Section 9(d)(3).

[10] *See* Original Obvious Error Proposal *supra* note 7; *see also* GEMX LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.*

[11] *See also* GEMX LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.* During the most recent Review Period the Exchange did not receive any obvious error review requests for Limit-Up-Limit Down trades, and Limit Up-Limit Down trade volume accounted for nominal overall trade volume.

[12] *See supra* note 3.

which effectiveness expires on October 18, 2019, and to make such rules permanent. In its approval order to make the Plan permanent, the Commission recognized that, as a result of the Participants' and industry analysis of the Plan's operation, the Limit Up-Limit Down mechanism effectively addresses extraordinary market volatility. Indeed, the Plan benefits markets and market participants by helping to ensure orderly markets, but also, the Exchange believes, based on the data made available to the public and the Commission during the pilot period, that the obvious error pilot does not negatively impact market quality during normal market conditions.[13] Rather, the Exchange believes the obvious error pilot functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. The Exchange also believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders and cancel Stop Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[14] This removes impediments to and perfects the mechanism of a free and open market and national market system by encouraging more investors to participate in light of the changes associated with the Plan. The Exchange believes that if approved on a permanent basis, the Options Pilots would permanently provide investors with the above-described additional certainty of market prices and mitigation of unanticipated consequences and unreasonable adverse selection risk during limit and straddle states.

Since the Commission's approval of Amendment 18 allowing the Plan to operate on a permanent basis, the Exchange and other national securities exchanges have determined that no further amendments should be made to the Options Pilots;[15] the current Options Pilots effectively address extraordinary market volatility, are reasonably designed to comply with the requirements of the Plan, facilitate compliance with the Plan and should now operate on a permanent basis, consistent with the Plan. The Exchange does not propose any substantive or additional changes to Options 3, Section 9(d) or Supplementary Material .01 to Options 3, Section 20.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[16] in general, and Section 6(b)(5) of the Act,[17] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed rule supports the objectives of perfecting the mechanism of a free and open market and the national market system because it promotes transparency and uniformity across markets concerning rules for options markets adopted to coincide with the Plan. The Exchange believes that eliminating the pilot basis for the Options Pilots and making such rules permanent facilitates compliance with the Plan by adding certainty to the markets during periods of market volatility, which has been approved and found by the Commission to be reasonably designed to prevent potentially harmful price volatility in NMS Stocks. It has been determined by the Commission that the Plan benefits markets and market participants by helping to ensure orderly markets, and, based on the data made available to the public and the Commission during the pilot period for Supplementary Material .01 to Options 3, Section 20, the Plan does not negatively impact options market quality during normal market conditions. Rather, the Plan, as it is implemented under the obvious error pilot, functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. During a limit or straddle state, determining theoretical value of an option may be a subjective rather than an objective determination given the lack of a reliable NBBO, which may create an unreasonable adverse selection opportunity and discourage participants from providing liquidity during limit and straddle states. Therefore, the Exchange believes eliminating obvious error review in such states would, in turn, eliminate uncertainty and confusion for investors and benefit investors by encouraging more participation in light of the changes associated with the Plan. As stated, the Exchange believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders and cancel Stop Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[18] Accordingly, the Exchange believes that making the Options Pilots permanent will further the goals of investor protection and fair and orderly markets as the rules effectively address extraordinary market volatility pursuant to the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is necessary to reflect that the Plan no longer operates as a pilot and has been approved to operate on a permanent basis by the Commission. As such, Options 3, Section 9(d) and Supplementary Material .01 to Options 3, Section 20, which implement protections in connection with the Plan, should be amended to operate on a permanent basis. The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.[19] Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

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

[13] *See supra* note 11.

[14] *See supra* notes 8 and 9.

[15] *See* Securities Exchange Act Release No. 85609 (April 11, 2019), 84 FR 16055 (April 17, 2019) (SR–GEMX–2019–04).

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *See supra* notes 8 and 9.

[19] In addition, the Exchange's proposal is substantially similar to Cboe's recently approved rule change. *See supra* note 4.

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 [20] and Rule 19b–4(f)(6) thereunder.[21]

A proposed rule change filed under Rule 19b–4(f)(6) [22] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [23] 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 proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current Options Pilots to continue on a permanent basis without any changes, prior to the pilot expiration on October 18, 2019. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[24]

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.

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii).

[24] 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).

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–2019–16 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–2019–16. 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–GEMX–2019–16 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Eduardo A. Aleman,

Deputy Secretary.

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BILLING CODE 8011–01–P

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87367; File No. SR–CboeEDGX–2019–062]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Current Pilot Program Related to EDGX Rule 11.15, Clearly Erroneous Executions, to the Close of Business on April 20, 2020

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2019, Cboe EDGX Exchange, Inc. (''Exchange'' or ''EDGX'') 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

Cboe EDGX Exchange, Inc. (''EDGX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to extend the current pilot program related to EDGX Rule 11.15, Clearly Erroneous Executions, to the close of business on April 20, 2020. The text of the proposed rule change is provided in Exhibit 5. [sic]

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, 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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to extend the effectiveness of the Exchange's current rule applicable to Clearly Erroneous Executions to the close of business on April 20, 2020. Portions of Rule 11.15, explained in further detail below, are currently operating as a pilot program set to expire on October 18, 2019.[3]

On September 10, 2010, the Commission approved, on a pilot basis, changes to EDGX Rule 11.15 that, among other things: (i) Provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[4] In 2013, the Exchange adopted a provision designed to address the operation of the Plan.[5] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) A series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[6]

On December 26, 2018, the Commission published the proposed Eighteenth Amendment[7] to the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ''Limit Up-Limit Down Plan'' or the ''Plan'')[8] to allow the Plan to operate on a permanent, rather than pilot, basis. On April 8, 2019, the Exchange amended EDGX Rule 11.15 to untie the pilot program's effectiveness from that of the Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019 in order allow the Exchange and other national securities exchanges additional time to consider further amendments, if any, to the clearly erroneous execution rules in light of the proposed Eighteenth Amendment to the Plan.[9] On April 17, 2019, the Commission published an approval of the Eighteenth Amendment to allow the Plan to operate on a permanent, rather than pilot, basis.[10]

The Exchange now proposes to amend EDGX Rule 11.15 to extend the pilot's effectiveness to the close of business on April 20, 2020. The Exchange understands that the other national securities exchanges and Financial Industry Regulatory Authority (''FINRA'') will also file similar proposals to extend their respective clearly erroneous execution pilot programs, the substance of which are identical to EDGX Rule 11.15.

The Exchange does not propose any additional changes to EDGX Rule 11.15. The Exchange believes the benefits to market participants from the more objective clearly erroneous executions rule should continue on a limited six month pilot basis. As the Plan was approved by the Commission to operate on a permanent, rather than pilot, basis the Exchange intends to assess whether additional changes should also be made to the operation of the clearly erroneous execution rules. Extending the effectiveness of EDGX Rule 11.15 for an additional six months should provide the Exchange and other national securities exchanges additional time to consider further amendments, if any, to the clearly erroneous execution rules.

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) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that extending the clearly erroneous execution pilot under EDGX Rule 11.15 for an additional six months would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Based on the foregoing, the Exchange believes the amended clearly erroneous executions rule should continue to be in effect on a pilot basis while the Exchange and the other national securities exchanges consider and develop a permanent proposal for clearly erroneous execution reviews.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange understands that FINRA and other national securities exchanges will also file similar proposals to extend their respective clearly erroneous execution pilot programs. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

[3] *See* Securities Exchange Act Release No. 85545 (Apr. 8, 2019), 84 FR 15016 (Apr. 12, 2019) (SR–CboeEDGX–2019–016).

[4] *See* Securities Exchange Act Release No. 62886 (Sept. 10, 2010), 75 FR 56613 (Sept. 16, 2010) (SR–EDGX–2010–03).

[5] *See* Securities Exchange Act Release No. 68814 (Feb. 1, 2013), 78 FR 9086 (Feb. 7, 2013) (SR–EDGX–2013–06).

[6] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–EDGX–2014–12).

[7] *See* Securities Exchange Act Release No. 84843 (December 18, 2018), 83 FR 66464 (December 26, 2018) (File No. 4–631) (''Eighteenth Amendment'').

[8] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[9] *See* supra note 5.

[10] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (File No. 4–631).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No comments were solicited or received 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)(3)(A)(iii) of the Act [14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6) [16] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [17] 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 proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current clearly erroneous execution pilot program to continue uninterrupted, without any changes, while the Exchange and the other national securities exchanges consider a permanent proposal for clearly erroneous execution reviews. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[18]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeEDGX–2019–062 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–CboeEDGX–2019–062. 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–CboeEDGX–2019–062 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Deputy Secretary.

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[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] 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).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87376; File No. SR–EMERALD–2019–34]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors, Interpretation and Policy .01, and Exchange Rule 530, Limit Up-Limit Down

October 21, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 16, 2019, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a 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 is filing a proposal to amend Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors, Interpretation and Policy .01, and Exchange Rule 530, Limit Up-Limit Down, to make permanent certain options market rules that are linked to the equity market Plan to Address Extraordinary Market Volatility.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings/emerald* at MIAX Emerald's principal office, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to make permanent certain options market rules in connection with the equity market Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or the ''Plan''). This change is being proposed in connection with the recently approved amendment to the Limit Up-Limit Down Plan that allows the Plan to continue to operate on a permanent basis (''Amendment 18'').[3]

In an attempt to address extraordinary market volatility in NMS Stock, and, in particular, events like the severe volatility on May 6, 2010, U.S. national securities exchanges and the Financial Industry Regulatory Authority, Inc. (collectively, ''Participants'') drafted the Plan pursuant to Rule 608 of Regulation NMS and under the Act.[4] On May 31, 2012, the Commission approved the Plan, as amended, on a one-year pilot basis.[5] Though the Plan was primarily designed for equity markets, the Exchange believed it would, indirectly, potentially impact the options markets as well. Thus, the Exchange has previously adopted and amended Exchange Rule 521, Interpretation and Policy .01, and Exchange Rule 530, to ensure the option markets were not harmed as a result of the Plan's implementation and implemented such rules on a pilot basis that has coincided with the pilot period for the Plan (collectively, the ''Options Pilots'').[6] Exchange Rule 530 essentially serves as a roadmap for the Exchange's universal changes due to the implementation of the Plan and provides for trading halts whenever a market-wide trading halt is initiated due to extraordinary market conditions pursuant to the Plan. Exchange Rule 521, Interpretation and Policy .01, provides that transactions executed during a limit or straddle state are not subject to the obvious and catastrophic error rules. A limit or straddle state occurs when at least one side of the National Best Bid (''NBB'') or Offer (''NBO'') bid/ask is priced at a non-tradable level. Specifically, a straddle state exists when the NBB is below the lower price band while the NBO is inside the price band or when the NBO is above the upper price band and the NBB is within the band, while a limit state occurs when the NBO equals the lower price band (without crossing the NBB), or the NBB equals the upper price band (without crossing the NBO).

The Exchange adopted the Options Pilots to protect investors because when an underlying security is in a limit or straddle state, there will not be a reliable price for the security to serve as a benchmark for the price of the option. Specifically, the Exchange adopted Exchange Rule 521, Interpretation and Policy .01, because the application of the obvious and catastrophic error rules would be impracticable given the potential for lack of a reliable NBBO in the options market during limit and straddle states. When adjusting or busting a trade pursuant to the obvious error rule, the determination of theoretical value of a trade generally references the NBB (for erroneous sell transactions) or NBO (for erroneous buy transactions) just prior to the trade in question, and is therefore not reliable when at least one side of the NBBO is priced at a non-tradeable level, as is the case in limit and straddle states. In such a situation, determining theoretical value may often times be a very subjective rather than an objective determination and could give rise to additional uncertainty and confusion for investors. As a result, application of the obvious and catastrophic error rules would be impracticable given the lack of a reliable NBBO in the options market during limit and straddle states, and may produce undesirable effects or unanticipated consequences.

The Exchange adopted additional measures via other Options Pilot rules that are designed to protect investors during limit and straddle states. For example, the Exchange will reject market orders and not elect stop orders[7] during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state. Furthermore, the Exchange believes that eliminating the application of obvious error rules during a limit or straddle state eliminates the re-evaluation of a transaction executed during such a state that could potentially create an unreasonable adverse selection opportunity due to lack of a reliable reference price on one side of the market or another and discourage participants from providing liquidity during limit and straddle states, which is contrary to the goal in limiting participants' adverse selection with the application of the obvious error rule during normal trading states. For these reasons, the Exchange believes the Options Pilots are designed to add certainty on the options markets, which encourages more investors to participate in light of the changes associated with the Plan. The Plan was originally implemented on a pilot-basis in order to allow the public, the participating exchanges, and the Commission to assess the operation of the Plan and whether the Plan should be modified prior to approval on a permanent basis. As stated, the Exchange adopted the Option Pilots to coincide with this pilot; to continue the protections therein while the industry gains further experience operating the Plan.

In connection with the order approving the establishment of the obvious error pilot, as well as the extensions of the obvious error pilot, the Exchange committed to submit monthly data regarding the program and to submit an overall analysis of the obvious error pilot in conjunction with the data submitted under the Plan and any other data as requested by the Commission. Pursuant to the Exchange's Form 1 Application for approval as a national securities exchange, approved by the Commission on December 20, 2018, each month since March of 2019, the Exchange committed to provide the Commission, and the public, a dataset containing the data for each straddle

[3] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (Order Approving Amendment No. 18).

[4] *See* Securities Exchange Act Release No. 64547 (May 25, 2011), 76 FR 31647 (June 1, 2011) (File No. 4–631).

[5] *See* Securities and Exchange Act Release No. 67091 (May 31, 2012) 77 FR 33498 (June 6, 2012).

[6] *See* Securities Exchange Act Release No. 85568 (April 9, 2019), 84 FR 15243 (April 15, 2019) (SR–EMERALD–2019–17).

[7] This includes rules in connection with special handling for market orders, market-on-close orders, stop orders, and stock-option orders, as well as for certain electronic order handling features in a Limit Up-Limit Down state, the obvious error rules, and providing that the Exchange will not require Market-Makers to quote in series of options when the underlying security is in a Limit Up-Limit Down state.

and limit state in optionable stocks that had at least one trade on the Exchange.[8] The Exchange has continued to provide the Commission with this data on a monthly basis since March 2019. For each trade on the Exchange, the Exchange provides (a) the stock symbol, option symbol, time at the start of the straddle or limit state, an indicator for whether it is a straddle or limit state, and (b) for the trades on the Exchange, the executed volume, time-weighted quoted bid-ask spread, time-weighted average quoted depth at the bid, time-weighted average quoted depth at the offer, high execution price, low execution price, number of trades for which a request for review for error was received during straddle and limit states, an indicator variable for whether those options outlined above have a price change exceeding 30% during the underlying stock's limit or straddle state compared to the last available option price as reported by OPRA before the start of the limit or straddle state. In addition, to help evaluate the impact of the pilot program, the Exchange has provided to the Commission, and the public, assessments relating to the impact of the operation of the obvious error rules during limit and straddle states including: (1) An evaluation of the statistical and economic impact of limit and straddle states on liquidity and market quality in the options markets, and (2) an assessment of whether the lack of obvious error rules in effect during the straddle and limit states are problematic. The Exchange has concluded that the Options Pilots do not negatively impact market quality during normal market conditions,[9] and that there has been insufficient data to assess whether a lack of obvious error rules is problematic, however, the Exchange believes the continuation of Exchange Rule 521, Interpretation and Policy .01 functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets.

The Commission recently approved the Plan on a permanent basis (Amendment 18).[10] In connection with this approval, the Exchange now proposes to amend Exchange Rule 521, Interpretation and Policy .01, and Exchange Rule 530 that currently implement the provisions of the Plan on a pilot basis to eliminate the pilot basis, which effectiveness expires on October 18, 2019, and to make such rules permanent. In its approval order to make the Plan permanent, the Commission recognized that, as a result of the Participants' and industry analysis of the Plan's operation, the Limit Up-Limit Down mechanism effectively addresses extraordinary market volatility. Indeed, the Plan benefits markets and market participants by helping to ensure orderly markets, but also, the Exchange believes, based on the data made available to the public and the Commission during the pilot period, that the obvious error pilot does not negatively impact market quality during normal market conditions.[11] Rather, the Exchange believes the obvious error pilot functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. The Exchange also believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject market orders and not elect stop orders[12] during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state. This removes impediments to and perfects the mechanism of a free and open market and national market system by encouraging more investors to participate in light of the changes associated with the Plan. The Exchange believes that if approved on a permanent basis, the Options Pilots would permanently provide investors with the above-described additional certainty of market prices and mitigation of unanticipated consequences and unreasonable adverse selection risk during limit and straddle states.

The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs. Since the Commission's approval of Amendment 18 allowing the Plan to operate on a permanent basis, the Exchange and other national securities exchanges have determined that no further amendments should be made to the Options Pilots;[13] the current Options Pilots effectively address extraordinary market volatility, are reasonably designed to comply with the requirements of the Plan, facilitate compliance with the Plan and should now operate on a permanent basis, consistent with the Plan. The Exchange does not propose any substantive or additional changes to Exchange Rule 521, Interpretation and Policy .01, or Exchange Rule 530.

The Exchange also proposes to amend Exchange Rule 530 to remove the following sentence from the first paragraph: ''The Exchange will provide the Commission with data and analysis during the duration of this pilot as requested.'' The purpose of this proposed change is to further align the Exchange's Limit Up-Limit Down rules with competing options exchanges that have proposed rules consistent with this proposal. For example, Cboe Exchange, Inc. (''Cboe'') removed a similar provision in a 2015 rule filing[14] and continued to provide the Commission, and the public, each month with a dataset containing the data for each straddle and limit state in optionable stocks that had at least one trade on the Exchange.

Additionally, the proposed changes would align the Exchange's rules with the similar rule by Cboe.[15]

2. Statutory Basis

MIAX Emerald believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[16] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[17] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable

[8] *See* Securities Exchange Act Release No. 84891 (December 20, 2018), 83 FR 67421 (December 28, 2018)(In the Matter of the Application of MIAX EMERALD, LLC for Registration as a National Securities Exchange); *see also* MIAX Emerald Form 1 Application, Exhibit E, Section D(1)(v)(f); MIAX Emerald, LULD Pilot Reports, available at *https://www.miaxoptions.com/pilot-reports*.

[9] *See also* MIAX Emerald, LULD Pilot Reports, available at *https://www.miaxoptions.com/pilot-reports*. During the most recent Review Period the Exchange did not receive any obvious error review requests for Limit-Up-Limit Down trades, and Limit Up-Limit Down trade volume accounted for nominal overall trade volume.

[10] *See supra* note 3.

[11] *See supra* note 9.

[12] *See supra* note 7.

[13] *See* Securities Exchange Act Release No. 85568 (April 9, 2019), 84 FR 15243 (April 15, 2019)(SR–EMERALD–2019–17).

[14] *See* Securities Exchange Act Release No. 74898 (May 7, 2015), 80 FR 27354 (May 13, 2015(SR–CBOE–2015–039) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to Nullification and Adjustment of Options Transactions Including Obvious Errors).

[15] *See* Securities Exchange Act Release No. 87311 (October 15, 2019)(SR–CBOE–2019–049) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, to Make Permanent Certain Options Market Rules That Are Linked to the Equity Market Plan to Address Extraordinary Market Volatility).

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [18] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed rule changes support the objectives of perfecting the mechanism of a free and open market and the national market system because they promote transparency and uniformity across markets concerning rules for options markets adopted to coincide with the Plan. The Exchange believes that eliminating the pilot basis for the Options Pilots and making such rules permanent facilitates compliance with the Plan by adding certainty to the markets during periods of market volatility, which has been approved and found by the Commission to be reasonably designed to prevent potentially harmful price volatility in NMS Stocks. It has been determined by the Commission that the Plan benefits markets and market participants by helping to ensure orderly markets, and, based on the data made available to the public and the Commission during the pilot period for Exchange Rule 521, Interpretation and Policy .01, the Plan does not negatively impact options market quality during normal market conditions. Rather, the Plan, as it is implemented under the obvious error pilot, functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. During a limit or straddle state, determining theoretical value of an option may be a subjective rather than an objective determination given the lack of a reliable NBBO, which may create an unreasonable adverse selection opportunity and discourage participants from providing liquidity during limit and straddle states. Therefore, the Exchange believes eliminating obvious error review in such states would, in turn, eliminate uncertainty and confusion for investors and benefit investors by encouraging more participation in light of the changes associated with the Plan. As stated, the Exchange believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject market orders and not elect stop orders [19] during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state. Accordingly, the Exchange believes that making the Options Pilots permanent will further the goals of investor protection and fair and orderly markets as the rules effectively address extraordinary market volatility pursuant to the Plan.

Further, the Exchange believes that the proposed rule change to remove text in the first paragraph of Exchange Rule 530 regarding the Exchange providing the Commission with data and analysis during the duration of the pilot as requested supports the objectives of perfecting the mechanism of a free and open market and the national market system because it furthers aligns the Exchange's Limit Up-Limit Down rules with competing options exchanges.[20]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is necessary to reflect that the Plan no longer operates as a pilot and has been approved to operate on a permanent basis by the Commission. As such, Exchange Rule 521, Interpretation and Policy .01 and Exchange Rule 530, which implement protections in connection with the Plan, should be amended to operate on a permanent basis. The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [21] and subparagraph (f)(6) of Rule 19b–4 thereunder.[22]

A proposed rule change filed under Rule 19b–4(f)(6) [23] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [24] 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 proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current Options Pilots to continue on a permanent basis without any changes, prior to the pilot expiration on October 18, 2019. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[25]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

[18] *Id.*

[19] *See supra* note 7.

[20] *See supra* note 14.

[21] 15 U.S.C. 78s(b)(3)(A)(iii).

[22] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[23] 17 CFR 240.19b–4(f)(6).

[24] 17 CFR 240.19b–4(f)(6)(iii).

[25] 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).

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–EMERALD–2019–34 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–EMERALD–2019–34. 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–EMERALD–2019–34 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[26]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–23262 Filed 10–24–19; 8:45 am]

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[26] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87373; File No. SR–MRX–2019–23]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make Permanent Certain Options Market Rules That Are Linked to the Equity Market Plan To Address Extraordinary Market Volatility

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2019, 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 make permanent certain options market rules that are linked to the equity market Plan to Address Extraordinary Market Volatility.

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

The purpose of the proposed rule change is to make permanent certain options market rules in connection with the equity market Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or the ''Plan''). This change is being proposed in connection with the recently approved amendment to the Limit Up-Limit Down Plan that allows the Plan to continue to operate on a permanent basis (''Amendment 18'').[3] This proposed rule change is substantially similar to a recently-approved rule change by Cboe Exchange, Inc. (''Cboe'').[4]

In an attempt to address extraordinary market volatility in NMS Stocks, and, in particular, events like the severe volatility on May 6, 2010, U.S. national securities exchanges and the Financial Industry Regulatory Authority, Inc. (collectively, ''Participants'') drafted the Plan pursuant to Rule 608 of Regulation NMS and under the Act.[5] On May 31, 2012, the Commission approved the Plan, as amended, on a one-year pilot basis.[6] Though the Plan was primarily designed for equity markets, the Exchange believed it would, indirectly, potentially impact the options markets as well. Thus, the Exchange has previously adopted and amended Options 3, Section 9(d) and Supplementary Material .01 to Options 3, Section 20 to ensure the option markets were not harmed as a result of the Plan's implementation and has implemented such rules on a pilot basis that has coincided with the pilot period

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (Order Approving Amendment No. 18).

[4] *See* Securities Exchange Act Release Nos. 86744 (August 23, 2019), 84 FR 45565 (August 29, 2019) (SR–CBOE–2019–049) (Notice of Filing); and 87311 (October 15, 2019) (SR–CBOE–2019–049) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2). The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.

[5] *See* Securities Exchange Act Release No. 64547 (May 25, 2011), 76 FR 31647 (June 1, 2011) (File No. 4–631).

[6] *See* Securities and Exchange Act Release No. 67091 (May 31, 2012) 77 FR 33498 (June 6, 2012).

for the Plan (the ''Options Pilots'').[7] Options 3, Section 9(d) addresses the interplay of the Exchange's rules in response to the Plan, and includes provisions on how the Exchange will treat certain options orders during a limit or straddle state as well as options market maker quoting obligations during a limit or straddle state. In addition, Supplementary Material .01 to Options 3, Section 20 provides that an execution will not be subject to obvious or catastrophic error review if it occurred during a limit or straddle state. A limit or straddle state occurs when at least one side of the National Best Bid (''NBB'') or Offer (''NBO'') bid/ask is priced at a non-tradable level. Specifically, a straddle state exists when the NBB is below the lower price band while the NBO is inside the prices band or when the NBO is above the upper price band and the NBB is within the band, while a limit state occurs when the NBO equals the lower price band (without crossing the NBB), or the NBB equals the upper price band (without crossing the NBO). The Exchange adopted the Options Pilots to protect investors because when an underlying security is in a limit up-limit down state, there will not be a reliable price for the security to serve as a benchmark for the price of the option. Specifically, the Exchange adopted Supplementary Material .01 to Options 3, Section 20 because the application of the obvious and catastrophic error rules would be impracticable given the potential for lack of a reliable NBBO in the options market during limit and straddle states. When adjusting or busting a trade pursuant to the obvious error rule, the determination of theoretical value of a trade generally references the NBB (for erroneous sell transactions) or NBO (for erroneous buy transactions) just prior to the trade in question, and is therefore not reliable when at least one side of the NBBO is priced at a non-tradeable level, as is the case in limit and straddle states. In such a situation, determining theoretical value may often times be a very subjective rather than an objective determination and could give rise to additional uncertainty and confusion for investors. As a result, application of the obvious and catastrophic error rules would be impracticable given the lack of a reliable NBBO in the options market during limit and straddle states, and may produce undesirable effects or unanticipated consequences. As noted above, the Exchange adopted additional measures via other Options Pilot rules that are designed to protect investors during limit and straddle states.[8] For example, the Exchange will reject Market Orders (as defined in Options 3, Section 7(a)) and cancel Stop Orders [9] during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state. Furthermore, the Exchange believes that eliminating the application of obvious error rules during a limit or straddle state eliminates the re-evaluation of a transaction executed during such a state that could potentially create an unreasonable adverse selection opportunity due to the lack of a reliable reference price on one side of the market or another and discourage participants from providing liquidity during limit and straddle states, which is contrary to the goal in limiting participants' adverse selection with the application of the obvious error rule during normal trading states. For these reasons, the Exchange believes the Options Pilots and related rules are designed to add certainty on the options markets, which encourages more investors to participate in light of the changes associated with the Plan. The Plan was originally implemented on a pilot-basis in order to allow the public, the participating exchanges, and the Commission to assess the operation of the Plan and whether the Plan should be modified prior to approval on a permanent basis. As stated, the Exchange adopted the Option Pilots to coincide with this pilot; to continue the protections therein while the industry gains further experience operating the Plan.

In connection with the order approving the establishment of the obvious error pilot, as well as the extensions of the obvious error pilot, the Exchange committed to submit monthly data regarding the program and to submit an overall analysis of the obvious error pilot in conjunction with the data submitted under the Plan and any other data as requested by the Commission. Pursuant to the Exchange's Form 1 Application, approved on January 29, 2016, each month, the Exchange committed to provide the Commission, and the public, a dataset containing the data for each straddle and limit state in optionable stocks that had at least one trade on the Exchange.[10] The Exchange has continued to provide the Commission with this data on a monthly basis. For each trade on the Exchange, the Exchange provides (a) the stock symbol, option symbol, time at the start of the straddle or limit state, an indicator for whether it is a straddle or limit state, and (b) for the trades on the Exchange, the executed volume, time-weighted quoted bid-ask spread, time-weighted average quoted depth at the bid, time-weighted average quoted depth at the offer, high execution price, low execution price, number of trades for which a request for review for error was received during straddle and limit states, an indicator variable for whether those options outlined above have a price change exceeding 30% during the underlying stock's limit or straddle state compared to the last available option price as reported by OPRA before the start of the limit or straddle state. In addition, to help evaluate the impact of the pilot program, the Exchange has provided to the Commission, and the public, assessments relating to the impact of the operation of the obvious error rules during limit and straddle states including: (1) An evaluation of the statistical and economic impact of limit and straddle states on liquidity and market quality in the options markets, and (2) an assessment of whether the lack of obvious error rules in effect during the straddle and limit states are problematic. The Exchange has concluded that the Options Pilots do not negatively impact market quality during normal market conditions,[11] and that there has been insufficient data to assess whether a lack of obvious error rules is problematic, however, the Exchange believes the continuation of the Options Pilots function to protect against any unanticipated consequences in the options markets during a limit or

[7] *See* Securities Exchange Act Release Nos. 76998 (January 29, 2016), 81 FR 6066 (February 4, 2016) (File No. 10–221) (In the Matter of the Application of ISE Mercury, LLC for Registration as a National Securities Exchange); and 81204 (July 25, 2017), 82 FR 35557 (July 31, 2017). The Exchange notes that it adopted the limit up-limit down obvious error pilot currently within Supplementary Material .01 to Options 3, Section 20 (originally within Rule 703A(d)) as part of the Exchange's Form 1 Application for registration as a national securities exchange. *See also* MRX Form 1 Application, *Exhibit B.*

[8] As set forth in Options 3, Section 9(d), this includes rules in connection with special handling for Market Orders and Stop Orders, and options market maker quoting obligations during a limit or straddle state.

[9] The Exchange will elect Stop Orders if the condition as provided in Options 3, Section 7(d) is met, and, because they become Market Orders, will then cancel them back. *See* Options 3, Section 9(d)(3).

[10] *See* MRX Form 1 Application *supra* note 7. *See also* MRX LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.*

[11] *See also* MRX LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.* During the most recent Review Period the Exchange did not receive any obvious error review requests for Limit-Up-Limit Down trades, and Limit Up-Limit Down trade volume accounted for nominal overall trade volume.

straddle state and add certainty on the options markets.

The Commission recently approved the Plan on a permanent basis (Amendment 18).[12] In connection with this approval, the Exchange now proposes to amend Options 3, Section 9(d) and Supplementary Material .01 to Options 3, Section 20 that currently implement provisions of the Plan on a pilot basis to eliminate the pilot basis, which effectiveness expires on October 18, 2019, and to make such rules permanent. In its approval order to make the Plan permanent, the Commission recognized that, as a result of the Participants' and industry analysis of the Plan's operation, the Limit Up-Limit Down mechanism effectively addresses extraordinary market volatility. Indeed, the Plan benefits markets and market participants by helping to ensure orderly markets, but also, the Exchange believes, based on the data made available to the public and the Commission during the pilot period, that the obvious error pilot does not negatively impact market quality during normal market conditions.[13] Rather, the Exchange believes the obvious error pilot functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. The Exchange also believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders and cancel Stop Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[14] This removes impediments to and perfects the mechanism of a free and open market and national market system by encouraging more investors to participate in light of the changes associated with the Plan. The Exchange believes that if approved on a permanent basis, the Options Pilots would permanently provide investors with the above-described additional certainty of market prices and mitigation of unanticipated consequences and unreasonable adverse selection risk during limit and straddle states.

Since the Commission's approval of Amendment 18 allowing the Plan to operate on a permanent basis, the Exchange and other national securities exchanges have determined that no further amendments should be made to the Options Pilots;[15] the current Options Pilots effectively address extraordinary market volatility, are reasonably designed to comply with the requirements of the Plan, facilitate compliance with the Plan and should now operate on a permanent basis, consistent with the Plan. The Exchange does not propose any substantive or additional changes to Options 3, Section 9(d) or Supplementary Material .01 to Options 3, Section 20.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[16] in general, and Section 6(b)(5) of the Act,[17] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed rule supports the objectives of perfecting the mechanism of a free and open market and the national market system because it promotes transparency and uniformity across markets concerning rules for options markets adopted to coincide with the Plan. The Exchange believes that eliminating the pilot basis for the Options Pilots and making such rules permanent facilitates compliance with the Plan by adding certainty to the markets during periods of market volatility, which has been approved and found by the Commission to be reasonably designed to prevent potentially harmful price volatility in NMS Stocks. It has been determined by the Commission that the Plan benefits markets and market participants by helping to ensure orderly markets, and, based on the data made available to the public and the Commission during the pilot period for Supplementary Material .01 to Options 3, Section 20, the Plan does not negatively impact options market quality during normal market conditions. Rather, the Plan, as it is implemented under the obvious error pilot, functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. During a limit or straddle state, determining theoretical value of an option may be a subjective rather than an objective determination given the lack of a reliable NBBO, which may create an unreasonable adverse selection opportunity and discourage participants from providing liquidity during limit and straddle states. Therefore, the Exchange believes eliminating obvious error review in such states would, in turn, eliminate uncertainty and confusion for investors and benefit investors by encouraging more participation in light of the changes associated with the Plan. As stated, the Exchange believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders and cancel Stop Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[18] Accordingly, the Exchange believes that making the Options Pilots permanent will further the goals of investor protection and fair and orderly markets as the rules effectively address extraordinary market volatility pursuant to the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is necessary to reflect that the Plan no longer operates as a pilot and has been approved to operate on a permanent basis by the Commission. As such, Options 3, Section 9(d) and Supplementary Material .01 to Options 3, Section 20, which implement protections in connection with the Plan, should be amended to operate on a permanent basis. The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.[19] Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

[12] *See supra* note 3.

[13] *See supra* note 11.

[14] *See supra* notes 8 and 9.

[15] *See* Securities Exchange Act Release No. 85614 (April 11, 2019), 84 FR 16110 (April 17, 2019) (SR–MRX–2019–07).

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *See supra* notes 8 and 9.

[19] In addition, the Exchange's proposal is substantially similar to Cboe's recently approved rule change. *See supra* note 4.

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 [20] and Rule 19b–4(f)(6) thereunder.[21]

A proposed rule change filed under Rule 19b–4(f)(6) [22] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [23] 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 proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current Options Pilots to continue on a permanent basis without any changes, prior to the pilot expiration on October 18, 2019. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[24]

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–MRX–2019–23 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–2019–23. 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–2019–23 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–23259 Filed 10–24–19; 8:45 am]

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[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii).

[24] 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).

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87364; File No. SR–CboeBYX–2019–018]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Current Pilot Program Related to BYX Rule 11.17, Clearly Erroneous Executions, to the Close of Business on April 20, 2020

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 16, 2019, 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 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

Cboe BYX Exchange, Inc. (''BYX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to extend the current pilot program related to BYX Rule 11.17, Clearly Erroneous Executions, to the close of business on April 20, 2020. The text of the proposed rule change is provided in Exhibit 5. [sic]

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/byx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to extend the effectiveness of the Exchange's current rule applicable to Clearly Erroneous Executions to the close of business on April 20, 2020. Portions of Rule 11.17, explained in further detail below, are currently operating as a pilot program set to expire on October 18, 2019.[3]

On September 10, 2010, the Commission approved, on a pilot basis, changes to BYX Rule 11.17 that, among other things: (i) Provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[4] In 2013, the Exchange adopted a provision designed to address the operation of the Plan.[5] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) A series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[6]

On December 26, 2018, the Commission published the proposed Eighteenth Amendment[7] to the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ''Limit Up-Limit Down Plan'' or the ''Plan'')[8] to allow the Plan to operate on a permanent, rather than pilot, basis. On April 8, 2019, the Exchange amended BYX Rule 11.17 to untie the pilot program's effectiveness from that of the Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019 in order allow the Exchange and other national securities exchanges additional time to consider further amendments, if any, to the clearly erroneous execution rules in light of the proposed Eighteenth Amendment to the Plan.[9] On April 17, 2019, the Commission published an approval of the Eighteenth Amendment to allow the Plan to operate on a permanent, rather than pilot, basis.[10]

The Exchange now proposes to amend BYX Rule 11.17 to extend the pilot's effectiveness to the close of business on April 20, 2020. The Exchange understands that the other national securities exchanges and Financial Industry Regulatory Authority (''FINRA'') will also file similar proposals to extend their respective clearly erroneous execution pilot programs, the substance of which are identical to BYX Rule 11.17.

The Exchange does not propose any additional changes to BYX Rule 11.17. The Exchange believes the benefits to market participants from the more objective clearly erroneous executions rule should continue on a limited six month pilot basis. As the Plan was approved by the Commission to operate on a permanent, rather than pilot, basis the Exchange intends to assess whether additional changes should also be made to the operation of the clearly erroneous execution rules. Extending the effectiveness of BYX Rule 11.17 for an additional six months should provide the Exchange and other national securities exchanges additional time to consider further amendments, if any, to the clearly erroneous execution rules.

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) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that extending the clearly erroneous execution pilot under BYX Rule 11.17 for an additional six months would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Based on the foregoing, the Exchange believes the amended clearly erroneous executions rule should continue to be in effect on a pilot basis while the Exchange and the other national securities exchanges consider and develop a permanent proposal for clearly erroneous execution reviews.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose

[3] *See* Securities Exchange Act Release No. 85542 (Apr. 8, 2019), 84 FR 15009 (Apr. 12, 2019) (SR–CboeBYX–2019–003).

[4] *See* Securities Exchange Act Release No. 63097 (Oct. 13, 2010), 75 FR 64767 (Oct. 20, 2010) (SR–BYX–2010–002).

[5] *See* Securities Exchange Act Release No. 68798 (Jan. 31, 2013), 78 FR 8628 (Feb. 6, 2013) (SR–BYX–2013–005).

[6] *See* Securities Exchange Act Release No. 71796 (March 25, 2014), 79 FR 18099 (March 31, 2014) (SR–BYX–2014–003).

[7] *See* Securities Exchange Act Release No. 84843 (December 18, 2018), 83 FR 66464 (December 26, 2018) (File No. 4–631) (''Eighteenth Amendment'').

[8] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[9] *See* supra note 5.

[10] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (File No. 4–631).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange understands that FINRA and other national securities exchanges will also file similar proposals to extend their respective clearly erroneous execution pilot programs. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No comments were solicited or received 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)(3)(A)(iii) of the Act [14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6) [16] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [17] 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 proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current clearly erroneous execution pilot program to continue uninterrupted, without any changes, while the Exchange and the other national securities exchanges consider a permanent proposal for clearly erroneous execution reviews. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[18]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBYX–2019–018 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–CboeBYX–2019–018. 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–CboeBYX–2019–018 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Deputy Secretary.

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[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] 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).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87093; File No. SR–BX–2019–031]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Pricing Schedule, at Equity 7, Section 118(a)

September 24, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1], and Rule 19b–4 thereunder,[2] notice is hereby given that on September 12, 2019, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's transaction fees and credits at Equity 7, Section 118(a), as described further below. The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.com/,* at the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange operates on the ''taker-maker'' model, whereby it generally pays credits to members that take liquidity and charges fees to members that provide liquidity. Currently, the Exchange has a schedule, at Equity 7, Section 118(a), which consists of several different credits that it provides for orders in securities priced at $1 or more per share that access liquidity on the Exchange and several different charges that it assesses for orders in such securities that add liquidity on the Exchange.

Over the course of the last few months, the Exchange has experimented with various reformulations of its pricing schedule with the aim of increasing activity on the Exchange, improving market quality, and increasing market share.[3] Although these changes have met with some success, the Exchange has yet to achieve the results it desires. Accordingly, the Exchange proposes to again restate its pricing schedule, in large part, in a further attempt to improve the attractiveness of the market to new and existing participants.

Description of the Changes

Credits for Accessing Liquidity Through the Exchange

The Exchange proposes to eliminate its schedule of existing credits (except as described below) and replace it with a new schedule of credits for orders in securities that remove liquidity from the Exchange (the ''New Credits''). Generally speaking, the proposed New Credits will be higher than the existing credits for orders in Tapes A and B and lower than the existing credits for orders in securities in Tape C.[4] The Exchange believes that higher overall credits will incentivize members to increase their liquidity removal activity in securities in Tapes A and B. Although credits for removal orders for securities in Tape C will be lower generally than they are now, the availability of the proposed New Credits will be tied to the level of a member's liquidity taking activity for orders in securities in Tape C; this proposal is aligned with the Exchange's objective to encourage an increase in liquidity in securities in Tape C (together with lower charges for adding liquidity in securities in Tape C, as discussed below).

Specifically, the Exchange proposes to adopt the following New Credits:

- A $0.0031 per share executed credit for orders in securities in Tapes A and B and a $0.0017 per share executed credit for orders in securities in Tape C that access liquidity (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a Non-displayed price) entered by a member that: (i) Accesses liquidity equal to or exceeding 0.225% of total Consolidated Volume during a month; (ii) accesses liquidity in Securities in Tape C equal to or exceeding 0.045% of total Consolidated Volume during a month; and (iii) adds liquidity equal to or exceeding an average daily volume of 50,000 shares in a month.
- A $0.0028 per share executed credit for orders in securities in Tapes A and B and a $0.0015 per share executed credit for orders in securities in Tape C that access liquidity (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a Non-displayed price) entered by a member that: (i) Accesses liquidity equal to or exceeding 0.11% of total Consolidated Volume during a month; (ii) accesses liquidity in Securities in Tape C equal to or exceeding 0.025% of total Consolidated Volume during a month; and (iii) adds liquidity equal to or exceeding an average daily volume of 50,000 shares in a month.
- A $0.0026 per share executed credit for orders in securities in Tapes A and B and a $0.0010 per share executed credit for orders in securities in Tape C that access liquidity (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a Non-displayed price) entered by a member that: (i) Accesses liquidity equal to or exceeding 0.08% of total Consolidated Volume during a month; (ii) accesses liquidity in Securities in Tape C equal to or exceeding 0.020% of total Consolidated Volume during a month; and (iii) adds liquidity equal to or exceeding an average daily volume of 50,000 shares in a month.
- A $0.0018 per share executed credit for orders in securities in Tapes A and B and a $0.0005 per share executed credit for orders in securities in Tape C that access liquidity (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a Non-displayed price) entered by a member that adds liquidity equal to or exceeding an average daily volume of 50,000 shares in a month.

As noted above, the proposed New Credits will not supplant all of the existing credits. Instead, the Exchange proposes that the following existing credits will continue to apply to orders in securities in all Tapes:

- $0.0000 per share executed for an order that receives price improvement and executes against an order with a Non-displayed price; and
- $0.0000 per share executed for an order with Midpoint pegging that removes liquidity.

The Exchange also proposes to continue charging a fee for orders in securities in any Tape (excluding an order with midpoint pegging and excluding an order that receives price improvement and executes against an order with a non-displayed price) that removes liquidity from the Exchange and that is entered by a member that does not add at least an average daily volume of 50,000 shares to the Exchange during a month. However, the Exchange proposes to increase that fee, again for orders in securities in all Tapes, from $0.0003 to $0.0005 per share executed.

[3] *See* Securities Exchange Act Release No. 34–86120 (June 17, 2019); 84 FR 29270 (June 21, 2019) (SR–BX–2019–026) [sic]; Securities Exchange Act Release No. 34–85912 (May 22, 2019); 84 FR 24834 (May 29, 2019) (SR–BX–2019–013).

[4] Whereas the highest credit under the existing schedule is $0.0027 per share executed for orders in securities in Tapes A, B, and C, the top credit in the proposed schedule for orders in securities in Tapes A and B is $0.0031 per share executed. Under the proposal, the highest credit available for orders in Tape C will be $0.0017 per share executed.

The Exchange notes that, whereas under the existing schedule, the Exchange provides a $0.0015 per share executed credit for orders in securities in all Tapes that access liquidity (excluding orders with Midpoint pegging and excluding orders that receive price improvement and execute against an order with a non-displayed price) entered by members that add at least an average daily volume of 50,000 shares to the Exchange during a month, the proposed schedule will provide a higher credit of $0.0018 per share executed for orders in Tapes A and B and a lower credit of $0.005 per share executed for orders in Tape C.

Charges for Adding Liquidity to the Exchange

Primarily as a means of encouraging the addition of liquidity in securities in Tape C, the Exchange proposes to largely replace its existing schedule of charges with a new schedule of charges for displayed and non-displayed orders in securities that add liquidity to the Exchange (the ''New Charges''). Generally speaking, the range of the proposed New Charges will be the same as the existing charges for orders in Tapes A and B and lower for orders in Tape C (with new and different qualifying volume thresholds for each charge).[5]

Specifically, the Exchange proposes to delete all of the existing charges for providing liquidity through the Exchange (except as provided below) and replace them with the following New Charges:

- A $0.0025 per share executed charge for displayed orders in securities in Tapes A and B that: Add liquidity entered by a member that (i) adds liquidity equal to or exceeding 0.17% of total Consolidated Volume and (ii) adds liquidity equal to or exceeding 0.025% of total Consolidated Volume in securities in Tape B during a month.
- A $0.0029 per share executed charge for displayed orders in securities in Tapes A and B that add liquidity entered by a member that (i) adds liquidity equal to or exceeding 0.08% of total Consolidated Volume and (ii) adds liquidity equal to or exceeding 0.020% of total Consolidated Volume in securities in Tape B during a month.
- A $0.0012 per share executed charge for displayed orders in securities in Tape C that add liquidity entered by a member that (i) adds liquidity equal to or exceeding 0.17% of total Consolidated Volume and (ii) adds liquidity equal to or exceeding 0.15% of total Consolidated Volume in securities in Tape C during a month.
- A $0.0014 per share executed charge for displayed orders in securities in Tape C that add liquidity entered by a member that (i) adds liquidity equal to or exceeding 0.12% of total Consolidated Volume and (ii) adds liquidity equal to or exceeding 0.07% of total Consolidated Volume in securities in Tape C during a month.
- A $0.0017 per share executed charge for displayed orders in securities in Tape C that add liquidity entered by a member that (i) adds liquidity equal to or exceeding 0.08% of total Consolidated Volume and (ii) adds liquidity equal to or exceeding 0.025% of total Consolidated Volume in securities in Tape C during a month.
- A $0.0030 per share executed charge for buy (sell) orders with Midpoint pegging in securities in all Tapes that receive an execution price that is lower (higher) than the midpoint of the NBBO.
- A $0.0030 per share executed charge for all other orders in securities in Tapes A and B.
- A $0.0020 per share executed charge for all other orders in securities in Tape C.

The Exchange proposes that following existing charges will continue to apply to orders in securities in all Tapes:

- A $0.0005 per share executed charge for orders with Midpoint pegging entered by a member that adds 0.02% of total Consolidated Volume of non-displayed liquidity excluding a buy (sell) order that receives an execution price that is lower (higher) than the midpoint of the NBBO.
- A $0.0015 per share executed charge for orders with Midpoint pegging entered by other member excluding a buy (sell) order that receives an execution price that is lower (higher) than the midpoint of the NBBO.
- A $0.0028 per share executed charge for non-displayed orders (other than orders with Midpoint pegging) entered by a member that adds liquidity equal to or exceeding 0.25% total Consolidated Volume during a month.
- A $0.0030 per share executed charge for all other non-displayed orders.
- Charges for entering BSTG, BSCN, BMOP, BTFY, BCRT, BDRK, BCST, and SCAR orders that execute in a venue other than the Nasdaq BX Equities System.

Applicability to and Impact on Participants

The proposed rule change is a broad restatement of the Exchange's schedule of credits and charges. The Exchange has designed the restated schedule to specifically increase liquidity removal activity on the Exchange for orders in securities in Tapes A and B, to increase liquidity adding activity in Tape C, and to thereby improve the overall quality and attractiveness of the Nasdaq BX market. The Exchange intends to accomplish this objective by providing overall higher credits to those participants that engage in large volumes of liquidity removal activity on the Exchange in securities in Tapes A and B and by charging lower overall fees to those participants that add liquidity to the Exchange in securities in Tape C.

Those participants that act as net removers of liquidity from the Exchange in securities in Tapes A and B will benefit directly from the proposed rule change through the receipts of higher credits. Those participants that act as net adders of liquidity to the Exchange in securities in Tape C will also benefit from lower charges and indirectly from any improvement in the overall quality of the market. However, net liquidity adders in securities in Tapes A and B and net removers of liquidity in securities in Tape C will bear the costs of these proposals. The Exchange notes that its proposal is not otherwise targeted at or expected to be limited in its applicability to a specific segment(s) of market participants nor will it apply differently to different types of market participants.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[6] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[7] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposal is also consistent with Section 11A of the Act relating to the establishment of the national market system for securities.

The Proposal Is Reasonable

The Exchange's proposed change to its schedule of credits and charges is reasonable in several respects. As a threshold matter, the Exchange is subject to significant competitive forces in the market for equity securities transaction services that constrain its pricing determinations in that market. The fact that this market is competitive has long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted'

[5] Whereas under the existing pricing schedule, other than for midpoint pegging orders, the Exchange charges between $0.0025 and $0.0030 per share executed for orders in securities in all Tapes, the proposed schedule will charge fees ranging from $0.0025 to $0.0030 per share executed for orders in securities in Tapes A and B and $0.0012 to $0.0020 for orders in securities in Tape C.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4) and (5).

because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers' . . . .''[8]

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.''[9]

Numerous indicia demonstrate the competitive nature of this market. For example, clear substitutes to the Exchange exist in the market for equity security transaction services. The Exchange is only one of several equity venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. It is also only one of several taker-maker exchanges. Competing equity exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume thresholds.[10]

Within this environment, market participants can freely and often do shift their order flow among the Exchange and competing venues in response to changes in their respective pricing schedules.[11] Separately, the Exchange has provided the SEC staff with multiple examples of instances where pricing changes by BX and other exchanges have resulted in shifts in exchange market share. Within the foregoing context, the proposal represents a reasonable attempt by the Exchange to increase its liquidity and market share relative to its competitors.

The Exchange has designed its proposed schedule of credits and charges to provide increased overall incentives to members to increase their liquidity removal and adding activity on the Exchange in securities in the three Tapes. An increase in liquidity removal and adding activity on the Exchange will, in turn, improve the quality of the Nasdaq BX market and increase its attractiveness to existing and prospective participants. Generally, the proposed New Credits and Charges will be comparable to, if not favorable to, those that its competitors provide.[12]

The Exchange notes that those participants that are dissatisfied with the New Charges or New Credits are free to shift their order flow to competing venues that offer them lower charges.

The Proposal Is an Equitable Allocation of Credits and Charges

The Exchange believes its proposal will allocate its New Credits and New Charges fairly among its market participants. It is equitable for the Exchange to increase its credits to participants whose orders remove liquidity from the Exchange as a means of incentivizing increased liquidity removal activity. Likewise, it is equitable for the Exchange to reduce charges to participants whose orders add liquidity to the Exchange as a means of incentivizing liquidity adding activity. An increase in overall liquidity removal and addition activity on the Exchange will improve the quality of the Nasdaq BX market and increase its attractiveness to existing and prospective participants.

Likewise, it is equitable for the Exchange to specifically increase overall credits for orders that remove liquidity from the Exchange in Tapes A and B as a means of increasing liquidity removal activity in those Tapes, and to specifically lower overall charges for orders that add liquidity to the Exchange in Tape C as a means of increasing liquidity adding activity in Tape C. Again, the Exchange intends for these changes to improve the overall quality and attractiveness of the Nasdaq BX market.

Although under the proposal, certain participants will pay higher charges or attain lower credits than they do now, those participants will also benefit from any improvements in the quality and attractiveness of the market that the New Credits and New Charges provide. Moreover, any participant that wishes to avoid paying higher charges or receiving lower credits is free to shift their order flow to competing venues that provide more favorable pricing.

The Proposed Fee Is Not Unfairly Discriminatory

The Exchange believes that the proposal is not unfairly discriminatory. As an initial matter, the Exchange believes that nothing about its volume-based tiered pricing model is inherently unfair; instead, it is a rational pricing model that is well-established and ubiquitous in today's economy among firms in various industries—from co-branded credit cards to grocery stores to cellular telephone data plans—that use it to reward the loyalty of their best customers that provide high levels of business activity and incent other customers to increase the extent of their business activity. It is also a pricing model that the Exchange and its competitors have long employed with the assent of the Commission. It is fair because it incentivizes customer activity that increases liquidity, enhances price discovery, and improves the overall quality of the equity markets.

The Exchange intends for the proposal to improve market quality for all members on the Exchange and by extension attract more liquidity to the market, improving market wide quality and price discovery. Although net removers of liquidity in Tapes A and B and net adders of liquidity in Tape C will benefit most from the proposal, this result is fair insofar as increased activity in securities in these Tapes will help to improve market quality and the attractiveness of the Nasdaq BX market to all existing and prospective participants. And although certain participants will bear the costs of the proposed rule change through higher charges or lower credits, this too is fair because these participants will also benefit from improvements in market quality. Moreover, any participant that does not wish to pay higher charges or receive lower credits is free to shift its order flow to a competing venue.

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.

[8] *NetCoalition* v. *SEC,* 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

[9] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[10] CBOE EDGA provides a standard rebate for liquidity removers of $0.0024 per share executed (or $0.0026 per share executed if a member qualifies for a volume tier), and a standard charge of $0.0030 per share executed for liquidity adders (or between $0.0022 and $0.0026 if a member qualifies for a volume tier). NYSE National has a standard charge of $0.0005 per share executed for liquidity removers ($0.0025–$0.0030 rebate if a member qualifies for a volume tier) and a standard charge of $0.0028 per share executed for liquidity adders (and a range of charges from $0.0020–$0.0026 if a member qualifies for a volume tier).

[11] The Exchange perceives no regulatory, structural, or cost impediments to market participants shifting order flow away from it. In particular, the Exchange notes that these examples of shifts in liquidity and market share, along with many others, have occurred within the context of market participants' existing duties of Best Execution and obligations under the Order Protection Rule under Regulation NMS.

[12] *See* n. 10, *supra.*

Intramarket Competition

The Exchange does not believe that its proposal will place any category of Exchange participant at a competitive disadvantage. As noted above, all members of the Exchange will benefit from any increase in market activity that the proposal effectuates. Members may grow or modify their businesses so that they can receive the higher credits or pay lower charges. Moreover, members are free to trade on other venues to the extent they believe that the fees assessed and credits provided are not attractive. As one can observe by looking at any market share chart, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes. The Exchange notes that the tier structure is consistent with broker-dealer fee practices as well as the other industries, as described above.

Intermarket Competition

Addressing whether the proposed fee could impose a burden on competition on other SROs that is not necessary or appropriate, the Exchange believes that its proposed modifications to its schedule of credits and charges will not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from the other 12 live exchanges and from off-exchange venues, which include 32 alternative trading systems. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

The proposed restated schedule of credits and charges is reflective of this competition because, as a threshold issue, the Exchange is a relatively small market so its ability to burden intermarket competition is limited. In this regard, even the largest U.S. equities exchange by volume only has 17–18% market share, which in most markets could hardly be categorized as having enough market power to burden competition. Moreover, as noted above, price competition between exchanges is fierce, with liquidity and market share moving freely between exchanges in reaction to fee and credit changes. This is in addition to free flow of order flow to and among off-exchange venues which comprised more than 37% of industry volume for the month of July 2019.

The Exchange intends for the proposed changes, in the aggregate, to increase member incentives to engage in the removal and addition of liquidity on the Exchange. These changes are procompetitive and reflective of the Exchange's efforts to make it an attractive and vibrant venue to market participants.

In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result. Accordingly, the Exchange does not believe that the proposed changes will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[13]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2019–031 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–BX–2019–031. 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–BX–2019–031 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Jill M. Peterson,

Assistant Secretary.

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[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87369; File No. SR–Phlx–2019–45]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Make Permanent Certain Options Market Rules That Are Linked to the Equity Market Plan To Address Extraordinary Market Volatility

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2019, Nasdaq PHLX LLC (''Phlx'' 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 make permanent certain options market rules that are linked to the equity market Plan to Address Extraordinary Market Volatility.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqphlx.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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to make permanent certain options market rules in connection with the equity market Plan to Address Extraordinary Market Volatility (the ''Limit Up-Limit Down Plan'' or the ''Plan''). This change is being proposed in connection with the recently approved amendment to the Limit Up-Limit Down Plan that allows the Plan to continue to operate on a permanent basis (''Amendment 18'').[3] This proposed rule change is substantially similar to a recently-approved rule change by Cboe Exchange, Inc. (''Cboe'').[4]

In an attempt to address extraordinary market volatility in NMS Stocks, and, in particular, events like the severe volatility on May 6, 2010, U.S. national securities exchanges and the Financial Industry Regulatory Authority, Inc. (collectively, ''Participants'') drafted the Plan pursuant to Rule 608 of Regulation NMS and under the Act.[5] On May 31, 2012, the Commission approved the Plan, as amended, on a one-year pilot basis.[6] Though the Plan was primarily designed for equity markets, the Exchange believed it would, indirectly, potentially impact the options markets as well. Thus, the Exchange has previously adopted and amended Rule 1047(d) to ensure the option markets were not harmed as a result of the Plan's implementation and has implemented such rules on a pilot basis that has coincided with the pilot period for the Plan (the ''Options Pilots'').[7] Rule 1047(d) addresses the interplay of the Exchange's rules in response to the Plan, and includes provisions on how the Exchange will treat certain options orders during a limit or straddle state as well as options market maker quoting obligations during a limit or straddle state. In addition, Rule 1047(d)(v) provides that during a limit or straddle state, electronic trades are not subject to obvious and catastrophic error review. A limit or straddle state occurs when at least one side of the National Best Bid (''NBB'') or Offer (''NBO'') bid/ask is priced at a non-tradable level. Specifically, a straddle state exists when the NBB is below the lower price band while the NBO is inside the prices band or when the NBO is above the upper price band and the NBB is within the band, while a limit state occurs when the NBO equals the lower price band (without crossing the NBB), or the NBB equals the upper price band (without crossing the NBO). The Exchange adopted the Options Pilots to protect investors because when an underlying security is in a limit up-limit down state, there will not be a reliable price for the security to serve as a benchmark for the price of the option. Specifically, the Exchange adopted Rule 1047(d)(v) because the application of the obvious and catastrophic error rules would be impracticable given the potential for lack of a reliable NBBO in the options market during limit and straddle states. When adjusting or busting a trade pursuant to the obvious error rule, the determination of theoretical value of a trade generally references the NBB (for erroneous sell transactions) or NBO (for erroneous buy transactions) just prior to the trade in question, and is therefore not reliable when at least one side of the NBBO is priced at a non-tradeable level, as is the case in limit and straddle states. In such a situation, determining theoretical value may often times be a very subjective rather than an objective determination and could give rise to additional uncertainty and confusion for investors. As a result, application of the obvious and catastrophic error rules would be impracticable given the lack of a reliable NBBO in the options market during limit and straddle states, and may produce undesirable effects or unanticipated consequences. As noted above, the Exchange adopted additional measures via other Options Pilot rules that are designed to protect investors during limit and straddle states.[8] For example, the Exchange will reject Market Orders (as defined in Options 8,

[3] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (Order Approving Amendment No. 18).

[4] *See* Securities Exchange Act Release Nos. 86744 (August 23, 2019), 84 FR 45565 (August 29, 2019) (SR–CBOE–2019–049) (Notice of Filing); and 87311 (October 15, 2019) (SR–CBOE–2019–049) (Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2). The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.

[5] *See* Securities Exchange Act Release No. 64547 (May 25, 2011), 76 FR 31647 (June 1, 2011) (File No. 4–631).

[6] *See* Securities and Exchange Act Release No. 67091 (May 31, 2012) 77 FR 33498 (June 6, 2012).

[7] *See* Securities Exchange Act Release Nos. 69118 (March 12, 2013), 78 FR 16723 (March 18, 2013) (SR–Phlx–2013–20); 69332 (April 5, 2013), 78 FR 22009 (April 12, 2013) (SR–Phlx–2013–21); and 69141 (March 15, 2013), 78 FR 17262 (March 20, 2013) (SR–Phlx–2013–29).

[8] As set forth in Rule 1047(d), this includes rules in connection with special handling for Market Orders and Stop Orders, and options market maker quoting obligations during a limit or straddle state.

Section 32(a)) and cancel Stop Orders [9] (as defined in Options 8, Section 32(c)(2)) during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state. Furthermore, the Exchange believes that eliminating the application of obvious error rules during a limit or straddle state eliminates the re-evaluation of a transaction executed during such a state that could potentially create an unreasonable adverse selection opportunity due to the lack of a reliable reference price on one side of the market or another and discourage participants from providing liquidity during limit and straddle states, which is contrary to the goal in limiting participants' adverse selection with the application of the obvious error rule during normal trading states. For these reasons, the Exchange believes the Options Pilots and related rules are designed to add certainty on the options markets, which encourages more investors to participate in light of the changes associated with the Plan. The Plan was originally implemented on a pilot-basis in order to allow the public, the participating exchanges, and the Commission to assess the operation of the Plan and whether the Plan should be modified prior to approval on a permanent basis. As stated, the Exchange adopted the Option Pilots to coincide with this pilot; to continue the protections therein while the industry gains further experience operating the Plan.

In connection with the order approving the establishment of the obvious error pilot, as well as the extensions of the obvious error pilot, the Exchange committed to submit monthly data regarding the program and to submit an overall analysis of the obvious error pilot in conjunction with the data submitted under the Plan and any other data as requested by the Commission. Pursuant to a rule filing, approved on April 8, 2014, each month, the Exchange committed to provide the Commission, and the public, a dataset containing the data for each straddle and limit state in optionable stocks that had at least one trade on the Exchange.[10] The Exchange has continued to provide the Commission with this data on a monthly basis. For each trade on the Exchange, the Exchange provides (a) the stock symbol, option symbol, time at the start of the straddle or limit state, an indicator for whether it is a straddle or limit state, and (b) for the trades on the Exchange, the executed volume, time-weighted quoted bid-ask spread, time-weighted average quoted depth at the bid, time-weighted average quoted depth at the offer, high execution price, low execution price, number of trades for which a request for review for error was received during straddle and limit states, an indicator variable for whether those options outlined above have a price change exceeding 30% during the underlying stock's limit or straddle state compared to the last available option price as reported by OPRA before the start of the limit or straddle state. In addition, to help evaluate the impact of the pilot program, the Exchange has provided to the Commission, and the public, assessments relating to the impact of the operation of the obvious error rules during limit and straddle states including: (1) An evaluation of the statistical and economic impact of limit and straddle states on liquidity and market quality in the options markets, and (2) an assessment of whether the lack of obvious error rules in effect during the straddle and limit states are problematic. The Exchange has concluded that the Options Pilots do not negatively impact market quality during normal market conditions,[11] and that there has been insufficient data to assess whether a lack of obvious error rules is problematic, however, the Exchange believes the continuation of the Options Pilots function to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets.

The Commission recently approved the Plan on a permanent basis (Amendment 18).[12] In connection with this approval, the Exchange now proposes to amend Rule 1047(d) that currently implements provisions of the Plan on a pilot basis to eliminate the pilot basis, which effectiveness expires on October 18, 2019, and to make such rules permanent. In its approval order to make the Plan permanent, the Commission recognized that, as a result of the Participants' and industry analysis of the Plan's operation, the Limit Up-Limit Down mechanism effectively addresses extraordinary market volatility. Indeed, the Plan benefits markets and market participants by helping to ensure orderly markets, but also, the Exchange believes, based on the data made available to the public and the Commission during the pilot period, that the obvious error pilot does not negatively impact market quality during normal market conditions.[13] Rather, the Exchange believes the obvious error pilot functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. The Exchange also believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders and cancel Stop Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[14] This removes impediments to and perfects the mechanism of a free and open market and national market system by encouraging more investors to participate in light of the changes associated with the Plan. The Exchange believes that if approved on a permanent basis, the Options Pilots would permanently provide investors with the above-described additional certainty of market prices and mitigation of unanticipated consequences and unreasonable adverse selection risk during limit and straddle states.

Since the Commission's approval of Amendment 18 allowing the Plan to operate on a permanent basis, the Exchange and other national securities exchanges have determined that no further amendments should be made to the Options Pilots;[15] the current Options Pilots effectively address extraordinary market volatility, are reasonably designed to comply with the requirements of the Plan, facilitate compliance with the Plan and should now operate on a permanent basis, consistent with the Plan. The Exchange

[9] The Exchange will elect Stop Orders, but, because they become Market Orders, will then cancel them back. *See* Rule 1047(d)(iii). The Exchange will also make a non-substantive change to update the cross reference to Stop Orders contained in Rule 1047(d)(iii) from Options 8, Section 32(c)(1) to Options 8, Section 32(c)(2).

[10] *See* Securities Exchange Act Release No. 71901 (April 8, 2014), 79 FR 20955 (April 14, 2014) (SR–Phlx–2014–21); *see also* Phlx LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.*

[11] *See also* Phlx LULD Reports, available at: *https://www.nasdaq.com/solutions/options/LULD.* During the most recent Review Period the Exchange did not receive any obvious error review requests for Limit-Up-Limit Down trades, and Limit Up-Limit Down trade volume accounted for nominal overall trade volume.

[12] *See supra* note 3.

[13] *See supra* note 11.

[14] *See supra* notes 8 and 9.

[15] *See* Securities Exchange Act Release No. 85629 (April 11, 2019), 84 FR 16068 (April 17, 2019) (SR–Phlx–2019–11).

does not propose any substantive or additional changes to Rule 1047(d).

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[16] in general, and Section 6(b)(5) of the Act,[17] in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that the proposed rule supports the objectives of perfecting the mechanism of a free and open market and the national market system because it promotes transparency and uniformity across markets concerning rules for options markets adopted to coincide with the Plan. The Exchange believes that eliminating the pilot basis for the Options Pilots and making such rules permanent facilitates compliance with the Plan by adding certainty to the markets during periods of market volatility, which has been approved and found by the Commission to be reasonably designed to prevent potentially harmful price volatility in NMS Stocks. It has been determined by the Commission that the Plan benefits markets and market participants by helping to ensure orderly markets, and, based on the data made available to the public and the Commission during the pilot period for Rule 1047(d)(v), the Plan does not negatively impact options market quality during normal market conditions. Rather, the Plan, as it is implemented under the obvious error pilot, functions to protect against any unanticipated consequences in the options markets during a limit or straddle state and add certainty on the options markets. During a limit or straddle state, determining theoretical value of an option may be a subjective rather than an objective determination given the lack of a reliable NBBO, which may create an unreasonable adverse selection opportunity and discourage participants from providing liquidity during limit and straddle states. Therefore, the Exchange believes eliminating obvious error review in such states would, in turn, eliminate uncertainty and confusion for investors and benefit investors by encouraging more participation in light of the changes associated with the Plan. As stated, the Exchange believes the other Options Pilots rules provide additional measures designed to protect investors during limit and straddle states. For example, the Exchange will reject Market Orders and cancel Stop Orders during a Limit Up-Limit Down state to ensure that only those orders with a limit price will be executed during a limit or straddle state given the uncertainty of market prices during such a state.[18] Accordingly, the Exchange believes that making the Options Pilots permanent will further the goals of investor protection and fair and orderly markets as the rules effectively address extraordinary market volatility pursuant to the Plan.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is necessary to reflect that the Plan no longer operates as a pilot and has been approved to operate on a permanent basis by the Commission. As such, Rule 1047(d), which implements protections in connection with the Plan, should be amended to operate on a permanent basis. The Exchange understands that the other national securities exchanges will also file similar proposals to make permanent their respective pilot programs.[19] Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

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[20] and Rule 19b–4(f)(6) thereunder.[21]

A proposed rule change filed under Rule 19b–4(f)(6)[22] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii)[23] 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 proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current Options Pilots to continue on a permanent basis without any changes, prior to the pilot expiration on October 18, 2019. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[24]

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:

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *See supra* notes 8 and 9.

[19] In addition, the Exchange's proposal is substantially similar to Cboe's recently approved rule change. *See supra* note 4.

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[22] 17 CFR 240.19b–4(f)(6).

[23] 17 CFR 240.19b–4(f)(6)(iii).

[24] 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).

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2019–45 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2019–45. 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–Phlx–2019–45 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–23255 Filed 10–24–19; 8:45 am]

BILLING CODE 8011–01–P

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87366; File No. SR–CboeEDGA–2019–017]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Current Pilot Program Related to EDGA Rule 11.15, Clearly Erroneous Executions, to the Close of Business on April 20, 2020

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2019, Cboe EDGA Exchange, Inc. (''Exchange'' or ''EDGA'') 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

Cboe EDGA Exchange, Inc. (''EDGA'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to extend the current pilot program related to EDGA Rule 11.15, Clearly Erroneous Executions, to the close of business on April 20, 2020. The text of the proposed rule change is provided in Exhibit 5. [sic]

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to extend the effectiveness of the Exchange's current rule applicable to Clearly Erroneous Executions to the close of business on April 20, 2020. Portions of Rule 11.15, explained in further detail below, are currently operating as a pilot program set to expire on October 18, 2019.[3]

On September 10, 2010, the Commission approved, on a pilot basis, changes to EDGA Rule 11.15 that, among other things: (i) Provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[4] In 2013, the Exchange adopted a provision designed to address the operation of the Plan.[5] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) A series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[6]

On December 26, 2018, the Commission published the proposed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 85544 (Apr. 8, 2019), 84 FR 15011 (Apr. 12, 2019) (SR–CboeEDGA–2019–005).

[4] *See* Securities Exchange Act Release No. 62886 (Sept. 10, 2010), 75 FR 56613 (Sept. 16, 2010) (SR–EDGA–2010–03).

[5] *See* Securities Exchange Act Release No. 68813 (Feb. 1, 2013), 78 FR 9073 (Feb. 7, 2013) (SR–EDGA–2013–06).

[6] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–EDGA–2014–11).

Eighteenth Amendment[7] to the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ''Limit Up-Limit Down Plan'' or the ''Plan'')[8] to allow the Plan to operate on a permanent, rather than pilot, basis. On April 8, 2019, the Exchange amended EDGA Rule 11.15 to untie the pilot program's effectiveness from that of the Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019 in order allow the Exchange and other national securities exchanges additional time to consider further amendments, if any, to the clearly erroneous execution rules in light of the proposed Eighteenth Amendment to the Plan.[9] On April 17, 2019, the Commission published an approval of the Eighteenth Amendment to allow the Plan to operate on a permanent, rather than pilot, basis.[10]

The Exchange now proposes to amend EDGA Rule 11.15 to extend the pilot's effectiveness to the close of business on April 20, 2020. The Exchange understands that the other national securities exchanges and Financial Industry Regulatory Authority (''FINRA'') will also file similar proposals to extend their respective clearly erroneous execution pilot programs, the substance of which are identical to EDGA Rule 11.15.

The Exchange does not propose any additional changes to EDGA Rule 11.15. The Exchange believes the benefits to market participants from the more objective clearly erroneous executions rule should continue on a limited six month pilot basis. As the Plan was approved by the Commission to operate on a permanent, rather than pilot, basis the Exchange intends to assess whether additional changes should also be made to the operation of the clearly erroneous execution rules. Extending the effectiveness of EDGA Rule 11.15 for an additional six months should provide the Exchange and other national securities exchanges additional time to consider further amendments, if any, to the clearly erroneous execution rules.

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) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that extending the clearly erroneous execution pilot under EDGA Rule 11.15 for an additional six months would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Based on the foregoing, the Exchange believes the amended clearly erroneous executions rule should continue to be in effect on a pilot basis while the Exchange and the other national securities exchanges consider and develop a permanent proposal for clearly erroneous execution reviews.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange understands that FINRA and other national securities exchanges will also file similar proposals to extend their respective clearly erroneous execution pilot programs. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No comments were solicited or received 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)(3)(A)(iii) of the Act[14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6)[16] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii)[17] 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 proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current clearly erroneous execution pilot program to continue uninterrupted, without any changes, while the Exchange and the other national securities exchanges consider a permanent proposal for clearly erroneous execution reviews. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may

[7] *See* Securities Exchange Act Release No. 84843 (December 18, 2018), 83 FR 66464 (December 26, 2018) (File No. 4–631) (''Eighteenth Amendment'').

[8] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[9] *See* supra note 5.

[10] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (File No. 4–631).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] 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).

temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeEDGA–2019–017 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–CboeEDGA–2019–017. 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–CboeEDGA–2019–017 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–23271 Filed 10–24–19; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87365; File No. SR–CboeBZX–2019–089]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Extend the Current Pilot Program Related to BZX Rule 11.17, Clearly Erroneous Executions, to the Close of Business on April 20, 2020

October 21, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 18, 2019, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') 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

Cboe BZX Exchange, Inc. (''BZX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposed rule change to extend the current pilot program related to BZX Rule 11.17, Clearly Erroneous Executions, to the close of business on April 20, 2020. The text of the proposed rule change is provided in Exhibit 5. [sic]

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to extend the effectiveness of the Exchange's current rule applicable to Clearly Erroneous Executions to the close of business on April 20, 2020. Portions of Rule 11.17, explained in further detail below, are currently operating as a pilot program set to expire on October 18, 2019.[3]

On September 10, 2010, the Commission approved, on a pilot basis, changes to BZX Rule 11.17 that, among other things: (i) Provided for uniform treatment of clearly erroneous execution reviews in multi-stock events involving twenty or more securities; and (ii) reduced the ability of the Exchange to deviate from the objective standards set forth in the rule.[4] In 2013, the Exchange adopted a provision designed to address the operation of the Plan.[5] Finally, in 2014, the Exchange adopted two additional provisions providing that: (i) A series of transactions in a particular security on one or more trading days may be viewed as one event if all such transactions were effected based on the same fundamentally incorrect or grossly misinterpreted issuance information resulting in a severe valuation error for all such transactions; and (ii) in the event of any disruption or malfunction in the operation of the electronic communications and trading facilities of an Exchange, another SRO, or responsible single plan processor in connection with the transmittal or

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[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 85543 (Apr. 8, 2019), 84 FR 15018 (Apr. 12, 2019) (SR–CboeBZX–2019–022).

[4] *See* Securities Exchange Act Release No. 62886 (Sept. 10, 2010), 75 FR 56613 (Sept. 16, 2010) (SR–BATS–2010–016).

[5] *See* Securities Exchange Act Release No. 68797 (Jan. 31, 2013), 78 FR 8635 (Feb. 6, 2013) (SR–BATS–2013–008).

receipt of a trading halt, an Officer, acting on his or her own motion, shall nullify any transaction that occurs after a trading halt has been declared by the primary listing market for a security and before such trading halt has officially ended according to the primary listing market.[6]

On December 26, 2018, the Commission published the proposed Eighteenth Amendment[7] to the Plan to Address Extraordinary Market Volatility Pursuant to Rule 608 of Regulation NMS under the Act (the ''Limit Up-Limit Down Plan'' or the ''Plan'')[8] to allow the Plan to operate on a permanent, rather than pilot, basis. On April 8, 2019, the Exchange amended BZX Rule 11.17 to untie the pilot program's effectiveness from that of the Plan and to extend the pilot's effectiveness to the close of business on October 18, 2019 in order allow the Exchange and other national securities exchanges additional time to consider further amendments, if any, to the clearly erroneous execution rules in light of the proposed Eighteenth Amendment to the Plan.[9] On April 17, 2019, the Commission published an approval of the Eighteenth Amendment to allow the Plan to operate on a permanent, rather than pilot, basis.[10]

The Exchange now proposes to amend BZX Rule 11.17 to extend the pilot's effectiveness to the close of business on April 20, 2020. The Exchange understands that the other national securities exchanges and Financial Industry Regulatory Authority (''FINRA'') will also file similar proposals to extend their respective clearly erroneous execution pilot programs, the substance of which are identical to BZX Rule 11.17.

The Exchange does not propose any additional changes to BZX Rule 11.17. The Exchange believes the benefits to market participants from the more objective clearly erroneous executions rule should continue on a limited six month pilot basis. As the Plan was approved by the Commission to operate on a permanent, rather than pilot, basis the Exchange intends to assess whether additional changes should also be made to the operation of the clearly erroneous execution rules. Extending the effectiveness of BZX Rule 11.17 for an additional six months should provide the Exchange and other national securities exchanges additional time to consider further amendments, if any, to the clearly erroneous execution rules.

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) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes that extending the clearly erroneous execution pilot under BZX Rule 11.17 for an additional six months would help assure that the determination of whether a clearly erroneous trade has occurred will be based on clear and objective criteria, and that the resolution of the incident will occur promptly through a transparent process. The proposed rule change would also help assure consistent results in handling erroneous trades across the U.S. equities markets, thus furthering fair and orderly markets, the protection of investors and the public interest. Based on the foregoing, the Exchange believes the amended clearly erroneous executions rule should continue to be in effect on a pilot basis while the Exchange and the other national securities exchanges consider and develop a permanent proposal for clearly erroneous execution reviews.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange understands that FINRA and other national securities exchanges will also file similar proposals to extend their respective clearly erroneous execution pilot programs. Thus, the proposed rule change will help to ensure consistency across market centers without implicating any competitive issues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No comments were solicited or received 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)(3)(A)(iii) of the Act[14] and subparagraph (f)(6) of Rule 19b–4 thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6)[16] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii)[17] 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 proposed rule change may become effective and operative immediately upon filing. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, as it will allow the current clearly erroneous execution pilot program to continue uninterrupted, without any changes, while the Exchange and the other national securities exchanges consider a permanent proposal for clearly

[6] *See* Securities Exchange Act Release No. 72434 (June 19, 2014), 79 FR 36110 (June 25, 2014) (SR–BATS–2014–014).

[7] *See* Securities Exchange Act Release No. 84843 (December 18, 2018), 83 FR 66464 (December 26, 2018) (File No. 4–631) (''Eighteenth Amendment'').

[8] *See* Securities Exchange Act Release No. 67091 (May 31, 2012), 77 FR 33498 (June 6, 2012) (the ''Limit Up-Limit Down Release'').

[9] *See* supra note 5.

[10] *See* Securities Exchange Act Release No. 85623 (April 11, 2019), 84 FR 16086 (April 17, 2019) (File No. 4–631).

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and 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. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

erroneous execution reviews. For this reason, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[18]

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CboeBZX–2019–089 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–2019–089. 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–CboeBZX–2019–089 and should be submitted on or before November 15, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–23270 Filed 10–24–19; 8:45 am]

BILLING CODE 8011–01–P

[18] 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).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–87374; File No. SR–CBOE–2019–035]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, Regarding Off-Floor Position Transfers

October 21, 2019

I. Introduction

On July 3, 2019, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend its rule relating to off-floor position transfers. The proposed rule change was published for comment in the **Federal Register** on July 23, 2019.[3] On August 6, 2019, the Exchange filed Amendment No. 1 to the proposed rule change.[4] On September 4, 2019, the Commission extended the time period within which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the propose rule change, to October 21, 2019.[5] On October 7, 2019, the Exchange filed Amendment No. 2 to the proposed rule change.[6] The Commission received two comment letters on the proposal.[7] This order institutes proceedings under Section 19(b)(2)(B) of the Act[8] to determine whether to approve or disapprove the proposed rule change.

II. Description of Proposed Rule Change, as Modified by Amendment Nos. 1 and 2

Cboe generally requires a Trading Permit Holder (''TPH'') to effect transactions in listed options on an exchange.[9] Notwithstanding that provision, Cboe permits certain types of transfers involving a TPH's positions to be effected off the Exchange (also referred to as ''off-floor'' transfers).[10] The Exchange now proposes to delineate in the rule additional types of permitted off-floor transfers.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 86400 (July 17, 2019), 84 FR 35438 (''Notice'').

[4] In Amendment No. 1, the Exchange deleted from the proposed rule change the proposal to permit off-floor risk-weighted asset (''RWA'') transfers. The exchange subsequently refiled the RWA transfer proposal as a separate proposed rule change filing in SR–CBOE–2019–044. *See* Securities Exchange Release No. 87107 (September 25, 2019), 84 FR 52149 (October 1, 2019) (order approving proposed rule change to adopt Cboe Rule 6.49B regarding off-floor RWA transfers). When the Exchange filed Amendment No. 1 to CBOE–2019–035, it also submitted the text of the amendment as a comment letter to the filing, which the Commission made publicly available at *https://www.sec.gov/comments/sr-cboe-2019-035/srcboe2019035-5917170-189047.pdf.*

[5] *See* Securities Exchange Act Release No. 86861 (September 4, 2019), 84 FR 47627 (September 10, 2019).

[6] In Amendment No. 2, the Exchange updated cross-references to Cboe rules throughout the proposed rule change to reflect separate amendments it made to its rulebook in connection with the Exchange's technology migration, which it subsequently completed on October 7, 2019. When the Exchange filed Amendment No. 2 to CBOE–2019–035, it also submitted the text of the amendment as a comment letter to the filing, which the Commission made publicly available at *https://www.sec.gov/comments/sr-cboe-2019-035/srcboe2019035-6258833-192955.pdf.* The Commission notes that in addition to the cross-references updated in Amendment No. 2, the Exchange relocated Rule 6.49A to Rule 6.7 in its post-migration rulebook and made conforming changes to its proposed rule change to reflect that new rule number.

[7] *See* Letter to Vanessa Countryman, Secretary, Commission, dated September 24, 2019, from John Kinahan, Chief Executive Officer, Group One Trading, L.P., *available at https://www.sec.gov/comments/sr-cboe-2019-035/srcboe2019035-6193332-192497.pdf* (''Group One Letter'') and Letter to Brent J. Fields, Secretary, Commission, dated August 19, 2019, from Gerald D. O'Connell, Compliance Coordinator, Susquehanna International Group, LLP, *available at https://www.sec.gov/comments/sr-cboe-2019-035/srcboe2019035-5985436-190350.pdf (''SIG Letter'').*

[8] 15 U.S.C. 78s(b)(2)(B).

[9] *See* Cboe Rule 5.12(a) (formerly Rule 6.49(a)).

[10] *See* Cboe Rule 6.7(a) (formerly Rule 6.49A(a)).

Specifically, the proposed rule change would specify several additional types of permitted off-floor transfers, including (1) transfers to correct a bona fide error in the recording of a transaction or the transferring of a position to another account, (2) transfers between accounts where there is no change in ownership provided the accounts are not in separate aggregation units or otherwise subject to information barrier or account segregation requirements, (3) consolidation of accounts where no change in ownership is involved, and (4) transfers through operation of law from death, bankruptcy, or otherwise.[11]

Proposed paragraph (b) purports to codify Exchange guidance regarding certain restrictions on permissible off-floor transfers related to netting of open positions and to margin and haircut treatment, including a prohibition against netting and transfers that result in preferential margin or haircut treatment.[12] Proposed paragraph (c) would provide guidance as to the permitted transfer price at which an off-floor transfer may be effected.[13]

Proposed paragraph (d) would specify when written notice would be required prior to effecting an off-floor transfer.[14] Similarly, proposed paragraph (e) would provide certain recordkeeping and information requirements.[15]

III. Summary of the Comments

To date, the Commission has received two comment letters on the proposal.[16] One commenter criticized the proposal as ''overly restrictive'' in how it applies ''to transfers involving no material change of beneficial ownership,'' which it referred to as '' '*no change*' transfers.'' [17] The commenter expressed particular concern to the extent the proposal would restrict ''transfers between *no change* [market maker] accounts using broadly defined separate account delineations, and coupling that with strict prohibitions on routine-use and netting,'' which the commenter argued would ''unnecessarily and unreasonably restrict the ability of affiliated options market makers . . . to perform risk-reducing *no change* transfers.'' [18] The commenter also believed that the proposal would ''undercut the Exchange's longstanding policy,'' which the commenter characterized as having ''historically provided broad abilities for *no change* off-floor transfers by [market makers] without the frequency, netting or separate account restrictions contained in the *proposal*.'' [19] Similarly, the commenter believed that the impact of the proposed ''separate account delineations'' concept could ''perhaps be worsened by a degree of ambiguity'' and accordingly ''needs more clarity'' in the proposal.[20] The commenter argued that there exists certain impracticalities or impediments to accomplish no change transfers through exchange trading, and therefore market makers are presented with ''choices that are often costly and inefficient'' and that may ultimately harm investors if ''added expenses translate into wider quotes . . . .'' [21] The commenter further expressed concern that ''prohibiting transfers of such *no change* positions, and allowing the off-setting positions to co-exist without an economic purpose, can serve to misleadingly inflate the economic realities of overall open interest.'' [22] Finally, the commenter argued that the proposal ''fails to provide justification for imposing'' what it considers to be ''substantial restrictions'' on transfers involving no material change in beneficial ownership, and it ''lacks the required statutory bases for so broadly restricting'' such transfers.[23]

Another commenter expressed similar concerns, in particular that the proposal ''does not permit the use of the off-floor transfer procedure repeatedly or routinely in circumvention of the normal auction market process.'' [24] The commenter argued that ''a no change transfer is inherently different than a trade that occurs in the normal auction market process, and further noted that it is ''unaware of any normal auction market process that would allow for a single market participant to transact with itself in order to move a position across two accounts maintained by that same market participant.'' [25] Rather, commenter noted that ''[i]n a no change transfer, there is no buyer and there is no seller. These positions are already owned by the market participant after being acquired through the normal auction market process.'' [26] The commenter believed that ''[m]ore clarity needs to be provided to the breadth of the current language prohibiting the 'non-routine, non-recurring' use of no change transfers.'' [27]

IV. Proceedings To Determine Whether To Disapprove SR–CBOE–2019–035 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act to determine whether the proposed rule change, as modified by Amendment Nos. 1 and 2, 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, as discussed below, and the comments on the proposal. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved.

Pursuant to Section 19(b)(2)(B) of the Act, the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis and input concerning the proposed rule change's consistency with the Act, in particular with Section 6(b)(5) of the Act,[28] 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, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission believes that proceedings are appropriate to solicit additional input from the public, as well as the Exchange, to consider further the substantive concerns with the proposal that were raised by the commenters, including the applicability of the proposal to transfers involving no material change in beneficial ownership, its impact in particular on market makers and liquidity, and the scope and applicability of the proposed restrictions on non-routine, non-recurring movements of positions ''in circumvention of the normal auction market process'' as well as the proposed prohibition on netting.

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory

[11] *See* proposed Cboe Rule 6.7(a).

[12] *See* proposed Cboe Rule 6.7(b). *See also* Cboe Options Regulatory Circular RG03–62 (July 24, 2003).

[13] *See* proposed Cboe Rule 6.7(c).

[14] *See* proposed Cboe Rule 6.7(d).

[15] *See* proposed Cboe Rule 6.7(e).

[16] *See supra* note 7.

[17] *See* SIG Letter, *supra* note 7, at 1.

[18] *See id.*

[19] *See id.* at 7.

[20] *See id.* at 3.

[21] *See id.* at 4.

[22] *See id.* at 8.

[23] *See id.* at 9.

[24] *See* Group One Letter, *supra* note 7, at 1.

[25] *See id.*

[26] *See id.* at 2.

[27] *See id.*

[28] 15 U.S.C. 78f(b)(5).

organization ['SRO'] that proposed the rule change.'' [29] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[30] and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the applicable rules and regulations.[31]

For the reasons discussed above, the Commission believes it is appropriate to institute proceedings pursuant to Section 19(b)(2)(B) of the Act to determine whether the proposal should be approved or disapproved.

V. Procedures: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data and arguments with respect to the concerns identified above, as well as any other concerns they may have with the proposed rule change. In particular, the Commission invites the written views of interested persons concerning whether the proposal, as modified by Amendment Nos. 1 and 2, is inconsistent with Sections 6(b)(5) [32] and 6(b)(8) [33] or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval which would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,[34] any request for an opportunity to make an oral presentation.[35]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal, as modified by Amendment Nos. 1 and 2, should be approved or disapproved by November 15, 2019. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by November 29, 2019. 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–CBOE–2019–035 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–CBOE–2019–035. 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–CBOE–2019–035 and should be submitted on or before November 15, 2019. Rebuttal comments should be submitted by November 29, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–23260 Filed 10–24–19; 8:45 am]

BILLING CODE 8011–01–P

[29] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[30] *See id.*

[31] *See id.*

[32] 15 U.S.C. 78f(b)(5).

[33] 15 U.S.C. 78f(b)(8).

[34] 17 CFR 240.19b–4.

[35] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants to the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[36] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16151 and #16152; NORTH CAROLINA Disaster Number NC–00112]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of North Carolina

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of North Carolina (FEMA–4465–DR), dated 10/04/2019.

Incident: Hurricane Dorian.

Incident Period: 09/01/2019 through 09/09/2019.

DATES: Issued on 10/17/2019.

Physical Loan Application Deadline Date: 12/03/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 07/06/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of North Carolina, dated 10/04/2019, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Beaufort, Camden, Columbus, Greene, Hoke, Lenoir, Onslow, Pasquotank, Perquimans, Pitt, Robeson, Wayne.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–23347 Filed 10–24–19; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16095 and #16096; WISCONSIN Disaster Number WI–00069]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Wisconsin

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Wisconsin (FEMA–4459–DR), dated 08/27/2019.

Incident: Severe Storms, Tornadoes, Straight-line Winds, and Flooding.

Incident Period: 07/18/2019 through 07/20/2019.

DATES: Issued on 10/17/2019.

Physical Loan Application Deadline Date: 10/28/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 05/27/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Wisconsin, dated 08/27/2019, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Marinette

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2019–23346 Filed 10–24–19; 8:45 am]

BILLING CODE 8026–03–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16133 and #16134; LOUISIANA Disaster Number LA–00097]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Louisiana

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Louisiana (FEMA–4462–DR), dated 09/19/2019.

Incident: Flooding.

Incident Period: 05/10/2019 through 07/24/2019.

DATES: Issued on 10/17/2019.

Physical Loan Application Deadline Date: 11/18/2019.

Economic Injury (EIDL) Loan Application Deadline Date: 06/19/2020.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of LOUISIANA, dated 09/19/2019, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Parishes: Saint Mary

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator, for Disaster Assistance.

[FR Doc. 2019–23345 Filed 10–24–19; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice 10816]

60-Day Notice of Proposed Information Collection: Request for Determination of Possible Loss of United States Nationality

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *December 24, 2019.*

ADDRESSES:

You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2019–0025'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: RiversDA@state.gov.*
- *Regular Mail:* Send written comments to: U.S. Department of State, CA/OCS/PMO, SA–17, 10th Floor, Washington, DC 20522–1710.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Derek Rivers at SA–17, 10th Floor, Washington, DC 20522–1710, who may be reached on 202–485–6332 or at *RiversDA@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Request for Determination of Possible Loss of United States Nationality.
- *OMB Control Number:* 1405–0178.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Overseas Citizens Services (CA/OCS).
- *Form Number:* DS–4079.
- *Respondents:* United States Citizens.
- *Estimated Number of Respondents:* 3,250.
- *Estimated Number of Responses:* 3,250.
- *Average Time Per Response:* 15 minutes.
- *Total Estimated Burden Time:* 812 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Voluntary, but if not completed, may not obtain or retain benefits.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The purpose of the DS–4079 questionnaire is to assist in determining a person's nationality/nationalities and possible loss of United States nationality. The information provided assists consular officers and the Department of State in determining if the U.S. citizen has lost his or her nationality by voluntarily performing an expatriating act with the intention of relinquishing United States nationality. 8 U.S.C. 1501 grants authority to collect this information.

Methodology

The Bureau of Consular Affairs will post this form on Department of State websites to give respondents the opportunity to complete the form online, or print the form and fill it out manually and submit the form in person or by fax or mail.

Michelle Bernier-Toth,

Managing Director.

[FR Doc. 2019–23391 Filed 10–24–19; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice 10924]

30-Day Notice of Proposed Information Collection: Application for a U.S. Passport: Corrections, Name Change Within 1 Year of Passport Issuance, and Limited Passport Holders

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to November 25, 2019.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

• *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.

• *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

SUPPLEMENTARY INFORMATION:

• *Title of Information Collection:* Application for a U.S. Passport: Corrections, Name Change Within 1 Year of Passport Issuance, And Limited Passport Holders.

• *OMB Control Number:* 1405–0160.

• *Type of Request:* Revision of a Currently Approved Collection.

• *Originating Office:* Bureau of Consular Affairs, Passport Services (CA/PPT).

• *Form Number:* DS–5504.

• *Respondents:* Individuals or Households.

• *Estimated Number of Respondents:* 138,000.

• *Estimated Number of Responses:* 138,000.

• *Average Time per Response:* 40 minutes.

• *Total Estimated Burden Time:* 92,000 hours per year.

• *Frequency:* On occasion.

• *Obligation to Respond:* Required to Obtain a Benefit.

We are soliciting public comments to permit the Department to:

• Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

• Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.

• Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

The Application for a U.S. Passport: Corrections, Name Change Within 1 Year of Passport Issuance, And Limited Passport Holders (DS–5504) is the form used by current passport holders who need to re-apply for a passport, at no charge. The following categories are permitted to re-apply for a new passport using the DS–5504: (a) The passport holder's name has changed within the first year of the issuance of the passport; (b) the passport holder needs correction of descriptive information on the data page of the passport; (c) the passport holder wishes to obtain a fully valid passport after obtaining a full-fee passport with a limited validity of two years or less.

Methodology

Passport Services collects information from U.S. citizens and non-citizen nationals when they complete and submit the DS–5504, ''Application for a U.S. Passport: Corrections, Name Change Within 1 Year of Passport Issuance, And Limited Passport Holders''. Passport applicants can either download the DS–5504 from the internet or obtain the form from an Acceptance Facility/Passport Agency. The form must be completed, signed, and be submitted by mail (or in person at Passport Agencies domestically or embassies/consulates overseas).

Rachel M. Arndt,

Deputy Assistant Secretary for Passport Services.

[FR Doc. 2019–23322 Filed 10–24–19; 8:45 am]

BILLING CODE 4710–06–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36361]

Perry County Railroad, LLC—Lease and Operation Exemption—Howling Coyote, LLC and Perry County Associates, LLC

Perry County Railroad, LLC (PCR), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to lease and operate approximately 20,700 feet, or 3.92 miles, of track (the Line) owned by Howling Coyote, LLC and Perry County Associates, LLC (the Owners) in the Perry County Industrial Park (the Park), in Perry County, Ala. There are no mileposts on the Line.

According to PCR, the Line is currently used to receive rail cars of material bound to the Owners' landfill. PCR states that the cars are delivered onto the property by Norfolk Southern Railroad (NSR) and are switched by the

Owners for material handling. PCR states that the Owners seek to retain a rail carrier to take over the onsite rail operation and to serve any future tenants of the Park. According to PCR, the Owners have leased the Line and the land in the Park to PCR to start service when this exemption becomes effective.

PCR certifies that, as a result of the proposed transaction, its projected revenue will not exceed that of a Class III carrier and will not exceed $5 million annually. PCR states that the proposed transaction does not contain any limit on future interchange with third-party connecting carriers.

The proposed transaction may be consummated on or after November 9, 2019, the effective date for the exemption (30 days after the verified notice was filed).[1]

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than November 1, 2019 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36361, must be filed with Surface Transportation Board either via e-filing or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on PCR's representative, John F. McHugh, 233 Broadway, Suite 2320, New York, NY 10279.

According to PCR, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: October 22, 2019.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2019–23374 Filed 10–24–19; 8:45 am]

BILLING CODE 4915–01–P

[1] The date of PCR's supplement (October 10, 2019) will be considered the filing date for the purpose of calculating the effective date of the exemption.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Request To Release Property at Charlotte Douglas International Airport, Charlotte, NC (CLT)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration is requesting public comment on a request by City of Charlotte, to release of land (176.113 acres) at Charlotte Douglas International Airport from federal obligations.

DATES: Comments must be received on or before November 25, 2019.

ADDRESSES: Comments on this notice may be mailed or delivered in triplicate to the FAA at the following address: FAA/Memphis Airports District Office, Attn: Duane Johnson, Team Lead Civil Engineer, 2600 Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Brent Cagle, Aviation Director, Charlotte Douglas International Airport at the following address: 5601 Wilkinson Blvd., Charlotte, NC 28208.

FOR FURTHER INFORMATION CONTACT: Duane Johnson, Team Lead Civil Engineer, Federal Aviation Administration, Memphis Airports District Office, 2600, Thousand Oaks Boulevard, Suite 2250, Memphis, TN 38118–2482. The application may be reviewed in person at this same location, by appointment.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the request to release property for disposal at Charlotte Douglas International Airport, 5601 Wilkinson Blvd., Charlotte, NC 28208, under the provisions of 49 U.S.C. 47107(h)(2). The FAA determined that the request to release property at Charlotte Douglas International Airport (CLT) submitted by the Sponsor meets the procedural requirements of the Federal Aviation Administration and the release of these properties does not and will not impact future aviation needs at the airport. The FAA may approve the request, in whole or in part, no sooner than thirty days after the publication of this notice.

The request consists of the following:

The City of Charlotte is proposing the release of airport property totaling 176.113 acres, more or less. This land is to be used by the Norfolk Southern Railway Company (NSRC) for the operation of an Intermodal Rail Facility (150.975 acres fee simple) and (25.138 acres easement). The property is currently being used for the same non-aeronautical purpose under a long term lease approved by the FAA on April 13, 2010. The release of land is necessary to comply with FAA Grant Assurances that do not allow federally acquired airport property to be used for non-aviation purposes. The sale of the subject property will result in the land at Charlotte Douglas International Airport (CLT) being changed permanently from aeronautical to non-aeronautical use and releases the lands from the conditions of the Airport Improvement Program (AIP) Grant Agreement Grant Assurances. In accordance with 49 U.S.C. 47107(c)(2)(B)(i) and (iii), the airport will receive fair market value for the property, which will be subsequently reinvested in FAA approved eligible AIP projects for aviation facilities at Charlotte Douglas International Airport (CLT). The proposed use of this property is compatible with airport operations. The property is located on Charlotte Douglas International Airport, bordered on the west by Runway 18R–36L, bordered on the east by Runway 18C–36C, bordered on the north by Taxiway N, and by West Boulevard to the south.

This request will release this property from federal obligations. This action is taken under the provisions of 49 U.S.C. 47107(h)(2).

Any person may inspect the request in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT**.

In addition, any person may, upon request, inspect the request, notice and other documents germane to the request in person at the Charlotte Douglas International Airport.

Issued in Memphis, Tennessee, on October 18, 2019.

Tommy L. Dupree,

Acting Manager, Memphis Airports District Office, Southern Region.

[FR Doc. 2019–23231 Filed 10–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Safety Oversight and Certification Advisory Committee; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Safety Oversight and Certification Advisory Committee (SOCAC) meeting.

SUMMARY: This notice announces a meeting of the SOCAC.

DATES: The meeting will be held on November 13, 2019, from 1:00 p.m. to 3:00 p.m. Eastern Standard Time.

Requests to attend the meeting must be received by November 1, 2019.

Requests for accommodations to a disability must be received by November 1, 2019.

Requests to speak during the meeting must submit a written copy of their remarks to the Designated Federal Officer (DFO) by November 1, 2019.

Requests to submit written materials to be reviewed during the meeting must be received no later than November 1, 2019.

ADDRESSES: The meeting will be held at the Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591. Information on the committee and copies of the meeting minutes will be available on the FAA Committee website at *https://www.faa.gov/regulations_policies/rulemaking/committees/documents/.*

FOR FURTHER INFORMATION CONTACT: Lakisha Pearson, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, telephone (202) 267–4191; fax (202) 267–5075; email *9-awa-arm-socac@faa.gov.* Any committee related request should be sent to the person listed in this section.

SUPPLEMENTARY INFORMATION:

I. Background

The SOCAC was created under the Federal Advisory Committee Act (FACA), in accordance with the FAA Reauthorization Act of 2018, Public Law 115–254, to provide advice to the Secretary on policy-level issues facing the aviation community that are related to FAA safety oversight and certification programs and activities.

II. Agenda

At the meeting, the agenda will cover the following topics:

- Overview of FACA
- Overview of SOCAC
- Briefing on FAA Certification Process
- Assignment of tasks

A detailed agenda will be posted on the committee's website listed in the **ADDRESSES** section at least one week in advance of the meeting.

III. Public Participation

The meeting will be open to the public on a first-come, first served basis, as space is limited. Please confirm your attendance with the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than November 1, 2019. Please provide the following information: Full legal name, country of citizenship, and name of your industry association, or applicable affiliation. If you are attending as a public citizen, please indicate so.

For persons participating by telephone, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section by email or phone for the teleconference call-in number and passcode. Callers are responsible for paying long-distance charges.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

There will be 15 minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for each commenter may be limited. Individuals wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name, address, and organizational affiliation of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the FAA Office of Rulemaking may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks for inclusion in the meeting records and for circulation to SOCAC members. All prepared remarks submitted on time will be accepted and considered as part of the record. Any member of the public may present a written statement to the committee at any time.

The public may present written statements to the SOCAC by providing 25 copies to the Designated Federal Officer, by sending an email to *9-awa-arm-socac@faa.gov,* or by bringing the copies to the meeting.

Issued in Washington, DC, on October 21, 2019.

Brandon Roberts,

Acting Executive Director, Office of Rulemaking.

[FR Doc. 2019–23314 Filed 10–24–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Transportation Projects in Florida

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for Judicial Review of actions by Florida Department of Transportation (FDOT), pursuant to 23 U.S.C. 327, and other Federal Agencies.

SUMMARY: The FHWA, on behalf of FDOT, is issuing this notice to announce actions taken by FDOT and other Federal Agencies that are final agency actions. These actions relate to the proposed Cortez Bridge improvement project on State Road (S.R.) 684 from S.R. 789 (Gulf Drive) in Bradenton Beach, Florida to 123rd Street West in unincorporated Manatee County, Florida (Federal-Aid Project Number 8886–227–A). These actions grant licenses, permits, and approvals for the project.

DATES: By this notice, FHWA, on behalf of FDOT, is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal Agency actions on the highway project will be barred unless the claim is filed on or before March 23, 2020. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FDOT: Jason Watts, Director, Office of Environmental Management, FDOT, 605 Suwannee Street, MS 37, Tallahassee, Florida 32399; telephone (850) 414–4316; email: *Jason.watts@dot.state.fl.us.*

The FDOT Office of Environmental Management's normal business hours are 8:00 a.m. to 5:00 p.m. (Eastern Standard Time), Monday through Friday, except State holidays.

SUPPLEMENTARY INFORMATION: Effective December 14, 2016, the FHWA assigned, and the FDOT assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that FDOT, and other Federal Agencies have taken final agency action subject to 23 U.S.C. 139 (*l*)(1) by issuing licenses, permits, and approvals for the project described below. The actions by FDOT and other Federal Agencies on the project, and the laws under which such actions were taken, are described in the Type 2 Categorical Exclusion (CE) approved on September 18, 2019, and in other project records. The Type 2 CE

and other documents for the project are available by contacting FDOT at the address provided above. The Type 2 CE can be viewed and downloaded from the project website at *http://www.cortezbridge.com/final_reports.shtm.* Additional project documents can be found at *cortezbridge.com.*

The project subject to this notice is:

Project Location: Manatee County, Florida—Cortez Bridge on State Road (S.R.) 684 in the City of Bradenton Beach, Florida. The project involves replacement of the existing Cortez Bridge, a two-lane undivided 17.5-foot high low-level drawbridge, with a two-lane 65-foot high-level fixed bridge, with the addition of 10-foot wide shoulders and 10-foot sidewalks in each direction. The new bridge will be constructed approximately 20 feet north of the existing bridge, which will remain in place during construction to accommodate all traffic. The existing bridge will be removed after traffic is shifted to the new bridge.

This notice applies to all Federal Agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. *General:* National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351; Federal-Aid Highway Act (FAHA) [23 U.S.C. 109 and 23 U.S.C. 128].

2. *Air:* Clean Air Act (CAA), 42 U.S.C. 7401–7671(q).

3. *Land:* Section 4(f) of the U.S. Department of Transportation Act of 1966 (4f) [49 U.S.C. 303 and 23 U.S.C. 138].

4. *Wildlife:* Endangered Species Act (ESA) [16 U.S.C. 1531–1544 and 1536]; Marine Mammal Protection Act [16 U.S.C. 1361], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act (MBTA) [16 U.S.C. 703–712]; Magnuson-Stevenson Fishery Conservation and Management Act of 1976, as amended [16 U.S.C. 1801 *et seq.*].

5. *Historic and Cultural Resources:* Section 106 of the National Historic Preservation Act of 1966, as amended (106) [16 U.S.C. 470(f) *et seq.*]; Archaeological Resources Protection Act of 1977 (ARPA) [16 U.S.C. 470(aa)–470(II)]; Archaeological and Historic Preservation Act (AHPA) [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. *Social and Economic:* Civil Rights Act of 1964 (Civil Rights) [42 U.S.C. 20009(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. *Wetlands and Water Resources:* Clean Water Act (Section 404, Section 401, Section 319) [33 U.S.C. 1251–1377]; Coastal Barriers Resources Act (CBRA) [16 U.S.C. 3501 *et seq.*]; Coastal Zone Management Act (CZMA) [16 U.S.C. 1451–1465]; Land and Water Conservation Fund (LWCF) [16 U.S.C. 4601–4604]; Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j)(6)]; Rivers and Harbors Act of 1899 [33 U.S.C. 401–406]; Wild and Scenic Rivers Act [16 U.S.C. 1271–1287]; Emergency Wetlands Resources Act [16 U.S.C. 3921, 3931]; Wetlands Mitigation, [23 U.S.C. 103(b)(6)(M) and 103(b)(11)]; Flood Disaster Protection Act [42 U.S.C. 4001–4128].

8. *Executive Orders (E.O.):* E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Issued on: October 18, 2019.

Karen M. Brunelle,

Director, Office of Project Development, Federal Highway Administration, Tallahassee, Florida.

[FR Doc. 2019–23243 Filed 10–24–19; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2019–0036]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on April 2, 2019, the Georgetown Loop Railroad (GLR) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR 230.112 (*Wheels and tires*) and § 230.113 (*Wheels and tire defects*) for one steam locomotive used in tourist/excursion service. FRA assigned the petition Docket Number FRA–2019–0036.

Specifically, GLR requests relief from §§ 230.112 and 230.113 to allow Locomotive Number GLR 12 to be maintained to Baldwin Locomotive Works (BLW) standards for narrow-gage locomotives. GLR 12 was built in 1927, and is a 36-inch narrow gage locomotive. GLR 12 was used on a shortline in freight and passenger service until its retirement in the 1950s. It was subsequently sold to private individuals and moved to California to be used on various tourist/excursion trains. In the 1980s, a new boiler was installed and extensive repairs were made to the running gear. It was used frequently throughout the 1990s at the Silver Wood Amusement Park until its sale to the Colorado Historical Society in 2005 and was in service on GLR from 2005–2007.

By letter on April 7, 2008, FRA brought GLR under the agency's jurisdiction. During an inspection of the entire locomotive, it was determined that the inside gage (back-to-back spacing) exceeds the safety limits under 49 CFR 230.112(b). The actual width of the locomotive is 33½ inches. The allowable range is 32½ to 32⅞ inches wide. The locomotive was built to BLW's narrow-gage standards, which allow wider back-to-back dimensions and narrower flange widths for narrow gage engines. These alternate standard dimensions were primarily used in areas with prevalent sharp curves and poor track conditions. In addition to the wider back-to-back dimension used by Baldwin, a narrow flange width (new) that measures 1½ inches is used versus the 1¾-inch flange, which is the standard Association of American Railroads narrow flange.

GLR also seeks relief from § 230.113(g) regarding the minimum thickness of the tire's flange. The requirement for condemning a flange for insufficient width is 15⁄16 of an inch based upon a new thickness of 1¾ inches. Because the new flange thickness on GLR 12's flanges was 1½ inches, GLR requests that the condemning limit for this locomotive be 13⁄16 of an inch based upon the reduced initial width. GLR states that it has safely operated this locomotive for several years without any wheel problems prior to coming under FRA's jurisdiction. GLR believes that there is no practical way to modify the chassis components to comply with the regulatory requirements as the basic design of the locomotive's brake and spring rigging and driving boxes will

not allow the driving tires and wheels to be significantly modified.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received by November 25, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2019–23302 Filed 10–24–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2019–0034]

Petition for Waiver of Compliance

Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that on April 11, 2019, Iowa Interstate Railroad, Ltd. (IAIS) petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 230, *Steam Locomotive Inspection and Maintenance Standards.* FRA assigned the petition Docket Number FRA–2019–0034.

Specifically, IAIS seeks relief from performing the fifth annual inspection as it pertains to the inspection of flexible staybolt caps every 5 years as required by 49 CFR 230.41(a), and it requests to extend the inspection interval to the tenth annual inspection. IAIS states it will perform all other inspections as required by 49 CFR 230.16, *Annual inspection.* IAIS's justification for requesting this relief is that the current level of safety would be maintained due to the low number of service days accrued in these two engines (IAIS 6988 and 7018) since the last flexible staybolt cap inspections. There will be a significant cost savings as the IAIS shop forces would not be required to remove the cab, piping, jacketing, and insulation to gain access to the caps to perform the staybolt cap inspections. IAIS estimates that it would take three months and five full-time employees to perform each inspection at a significant cost.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received by November 25, 2019 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2019–23301 Filed 10–24–19; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request on Requirements for Qualified Domestic Trusts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the collection of information related to the requirements to ensure collection of section 2056A estate tax.

DATES: Written comments should be received on or before December 24, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Philippe Thomas, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Requirements for qualified domestic trust.

OMB Number: 1545–1443.

Regulatory Number: TD 8686.

Abstract: This document contains final regulations that provide guidance relating to the additional requirements necessary to ensure the collection of the estate tax imposed under section 2056A(b) with respect to taxable events involving qualified domestic trusts (QDOTs) described in section 2056A(a). In order to ensure collection of the tax, the regulation provides various security options that may be selected by the trust and the requirements associated with each option. In addition, under certain circumstances the trust is required to file an annual statement with the IRS disclosing the assets held by the trust.

Current Actions: There is no change to the burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and Households.

Estimated Number of Respondents: 4,390.

Estimated Time per Respondent: 1 hr., 23 mins.

Estimated Total Annual Burden Hours: 6,070.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) 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 using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: October 18, 2019.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2019–23397 Filed 10–24–19; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Creating Options for Veterans Expedited Recovery (COVER) Commission, Notice of Meeting

In accordance with the Federal Advisory Committee Act, the Creating Options for Veterans Expedited Recovery (COVER) Commission gives notice of a meeting to be held on November 5 and 6, 2019, at the VHA National Conference Center, 2011 Crystal Drive, Crystal City, Virginia 22202. The meetings will begin and end as follows:

Dates:	Times:
November 5, 2019	10:00 a.m.–5:00 p.m. EST.
November 6, 2019	8:30 a.m.–12:00 p.m. EST.

Eastern Standard Time (EST).

All meeting sessions are open to the public.

The purpose of the COVER Commission is to examine the evidence-based therapy treatment model used by the Department of Veterans Affairs (VA) for treating mental health conditions of Veterans and the potential benefits of incorporating complementary and integrative health approaches as standard practice throughout the Department.

Members of the public are invited to attend open sessions in-person or via telephone listening line. Only a limited amount of seating will be available, and members of the public will be seated on a first come-first served basis. The listening line number for both days is (844) 376–0278 access code 66335484#. The listening lines will be activated approximately 10 minutes prior to each day's sessions. Members of the public utilizing the listening line are asked to confirm their attendance via an email to *COVERCommission@va.gov.* The videotaping or recording of Commission proceedings is discouraged as it may be disruptive to the Commission's work.

Any member of the public seeking additional information including copies of materials referenced during open sessions should email the Designated Federal Officer for the Commission, Mr. John Goodrich, at *COVERCommission@va.gov.* Although there will not be time allotted for members of the public to speak, the COVER Commission will accept written comments which may be sent to the email address noted. In communications with the Commission, the writers must identify themselves and state the organizations, associations, or persons they represent.

Dated: October 22, 2019.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2019–23359 Filed 10–24–19; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 84 Friday,

No. 207 October 25, 2019

Part II

Department of Health and Human Services

42 CFR Chapter I

Mandatory Guidelines for Federal Workplace Drug Testing Programs—Oral/Fluid; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Chapter I

[SAMHSA—4162–20–P]

RIN 0930–AA24

Mandatory Guidelines for Federal Workplace Drug Testing Programs—Oral/Fluid

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

ACTION: Issuance of guidelines.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') has established scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines).

DATES: *Effective* January 1, 2020.

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SUPPLEMENTARY INFORMATION: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) will allow federal executive branch agencies to collect and test an oral fluid specimen as part of their drug testing programs. In addition, some agencies, such as the Department of Transportation, are required to follow the Guidelines in developing drug testing programs for their regulated industries, whereas others, such as the Nuclear Regulatory Commission (NRC), use the Guidelines as part of the regulatory basis for their drug testing programs for their regulated industries. The OFMG establish standards and technical requirements for oral fluid collection devices, initial oral fluid drug test analytes and methods, confirmatory oral fluid drug test analytes and methods, processes for review by a Medical Review Officer (MRO), and requirements for federal agency actions.

The OFMG provide flexibility for federal agency workplace drug testing programs to address testing needs and revise the requirement to collect only a urine specimen, which has existed since the Guidelines were first published in 1988. Since 1988, several products have appeared on the market making it easier for individuals to adulterate their urine specimens. The scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established and the advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in federal programs with the same level of confidence that has been applied to the use of urine. For example, oral fluid collection devices and procedures have been developed that protect against biohazards, maintain the stability of analytes, and provide sufficient oral fluid for testing. Additionally, specimen volume is also much lower, saving time in collection and transport cost. Developments in analytical technologies have provided efficient and cost-effective methods with the analytical sensitivity and accuracy required for testing oral fluid specimens.

Federal agencies, MROs, and regulated industries using the OFMG will continue to adhere to all other federal standards established for workplace drug testing programs. The OFMG provide the same scientific and forensic supportability of drug test results as the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG).

Background

The Department of Health and Human Services, by authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for federal agencies. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** [FR] on April 11, 1988 [53 FR 11979]. The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858]. The revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) were published on January 23, 2017 [82 FR 7920] with an effective date of October 1, 2017.

The Department published the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) in the May 15, 2015 **Federal Register** (80 FR 28054). There was a 60-day public comment period, during which 120 commenters submitted comments on the OFMG. These commenters were comprised of individuals, organizations, and private sector companies. The comments are available for public view at *http://www.regulations.gov/.* All comments were reviewed and taken into consideration in the preparation of the Guidelines. The issues and concerns raised in the public comments for the OFMG are set forth below. Similar comments are considered together in the discussion.

Summary of Public Comments and HHS's Response

The following comments were directed to the information and questions in the preamble.

Requirements for Specimen Validity Testing

The Department requested comments on requirements for federal agencies to test all oral fluid specimens for either albumin or immunoglobulin G (IgG) to determine specimen validity. Four commenters agreed with the proposed requirements. Twelve commenters disagreed with the Guidelines as written, suggesting that specimen validity testing is not needed because all oral fluid collections are observed, collection procedures require visual inspection of the mouth by the collector and a 10-minute wait period, collection devices contain a volume indicator, and there is a limited volume of oral fluid collected and this volume is needed to complete confirmatory drug tests. One commenter expressed concern over the consequences of erroneous validity test results in relation to inappropriate cutoffs being set. One commenter questioned the proposed specimen validity testing analytes and cutoffs, and proposed that volume sufficiency be determined upon receipt at the laboratory. One commenter disagreed with the proposed IgG cutoff. One commenter disagreed that specimen validity testing should be performed on all specimens, and recommended performing specimen validity testing on a randomly chosen subset. This commenter also stated that specimen validity testing must be subjected to oversight by proficiency testing and blind sample testing programs. The Department has evaluated the comments and has revised the Guidelines to allow, but not require, specimen validity testing. The Department agrees that the OFMG collection procedures greatly minimize the risks of donor attempts to tamper with the specimen, and the volume indicator requirement for oral fluid collection devices should prevent collection of insufficient volume. To avoid prohibiting use of albumin and

IgG tests, as well as other scientifically supportable oral fluid biomarker or adulterant tests that may become available, the Department is authorizing specimen validity testing upon request of the Medical Review Officer as described in Sections 3.1 and 3.5. All tests must be properly validated and include appropriate quality control samples in accordance with these Guidelines. In response to commenters' concerns about expending the limited volume of oral fluid collected, it should be noted that HHS-certified laboratories currently performing specimen validity tests for non-regulated oral fluid testing use low volumes (*i.e.,* 25 mcL for albumin tests, 15 mcL for IgG tests) that would not be expected to have a significant impact on a laboratory's ability to complete testing.

Proposed Cutoff Concentrations

Nineteen commenters submitted comments on the proposed drug test cutoffs. Some were general comments, while others concerned specific drug analytes. Cutoffs for marijuana tests are discussed in the following section, *Testing for Marijuana Use.* The comments and the Department's responses concerning cutoffs for other drug tests are described below.

Two commenters agreed with all proposed analytes and cutoffs. Two deferred setting cutoffs to HHS-certified laboratories. Three disagreed with all proposed cutoffs. Two of these commenters recommended retaining the cutoffs in the proposed Guidelines of April 13, 2004 (69 FR 19673). One of these commenters believes that the technology to detect analytes at these low levels is questionable and that these cutoffs will identify employees on prescribed medications. One commenter requested the basis for changing the cutoffs from those proposed in 2004. As described in the preamble to the proposed OFMG (80 FR 28054), the Department based the proposed cutoffs for each drug on information in public comments from the April 2004 proposed Guidelines, public responses to the June 2011 Request for Information (76 FR 34086), and the recommendations of a technical workgroup consisting of subject matter experts and representatives from various stakeholder groups (*e.g.,* collection device and test kit manufacturers, oral fluid drug testing laboratories). The Department provided the recommended cutoffs with supporting scientific information to the SAMHSA Drug Testing Advisory Board (DTAB) for review and discussion and, in the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, pages 28061–28065), included reasons for the proposed cutoffs for each drug, with references to supporting scientific studies. The Department has raised the cutoffs for some drug tests to address specific comments as described below. The Department concluded that no change is needed for other analytes. The cutoffs in Section 3.4 are supported by scientific studies, and are consistent with the goals of the federal workplace drug testing programs. The National Laboratory Certification Program (NLCP) Pilot Performance Testing (PT) Program has documented that laboratories are able to meet the Guidelines requirements using the cutoffs in Section 3.4.

One commenter agreed with the proposed initial test cutoff for cocaine, and recommended that a slightly lower cutoff be used for the confirmatory test. The Department did not find scientific evidence to warrant a change to the proposed confirmatory cutoff, which is the same as that proposed in 2004.

Five commenters disagreed with the proposed codeine and morphine cutoffs. Two commenters stated that the cutoffs are too low: One expressed concern over the technology to detect analytes at the proposed low levels and both noted that the change from currently used cutoffs will increase the number of initial test positives, thereby increasing costs. Two commenters stated that the Department has not supported changing from the cutoffs proposed in 2004 (*i.e.,* 40 ng/mL for both the initial and confirmatory tests), which are currently used by the industry. One commenter indicated that their test data support a cutoff of 30 ng/mL for both the initial and confirmatory tests. In the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, page 28063), the Department included reasons for the selected test cutoffs for each drug, with references supporting those cutoffs. The Department is retaining the proposed cutoffs (*i.e.,* 30 ng/mL for the initial test and 15 ng/mL for the confirmatory test) and is providing further explanation below to address the comments.

Reports in the literature provide information supporting lowering the morphine initial test cutoff from 40 to 30 ng/mL. In one dosing study with doses of 20 and 10 mg of morphine sulfate, morphine concentrations in saliva peaked at 0.5 hours at 37.8 ng/mL and 10.8 ng/mL, respectively, with detection times of 24 hours using a limit of detection (LOD) of 0.6 ng/mL.[1] In another report, morphine concentrations in oral fluid of treatment patients (n=4,575) were reported to range from 2 to 3,026 ng/mL with a median concentration of 49.8 ng/mL.[2] It was also found that 25% of the specimens contained morphine less than 13.5 ng/mL. These reports of short detection times and low concentrations of morphine in oral fluid also justify lowering the confirmatory cutoff for morphine to 15 ng/mL. The NLCP Pilot PT program has demonstrated oral fluid testing laboratories' abilities to meet codeine and morphine confirmatory cutoffs of 15 ng/mL using current testing technologies.

One commenter agreed with the proposed initial test cutoffs for oxycodone, oxymorphone, hydrocodone, and hydromorphone, but recommended that the same cutoffs be used for confirmatory testing. One commenter disagreed with all proposed cutoffs for these drugs, stating that the cutoffs are too low and will identify legitimate prescription users. The Department will retain the cutoffs as proposed. In the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, pages 28064–28065), the Department included reasons for the selected test cutoffs for each drug, with references supporting those cutoffs. Considerable research and discussion were conducted regarding the complex issues surrounding the specification of each cutoff concentration. The Department solicited input from laboratories, reagent and device manufacturers, subject matter experts, and the Food and Drug Administration (FDA). The cutoff concentrations are the outcome of the lengthy discussion process and represent the best approach currently available. Furthermore, the OFMG include the same requirements as the UrMG for Medical Review Officers to interview donors to determine whether there is a legitimate medical explanation for a positive test result, and to review documentation provided by the donor to support a legitimate medical explanation.

One commenter disagreed with the proposed 3 ng/mL initial test cutoff for 6-acetylmorphine (6–AM), stating that the proposed cutoff is higher than that currently used. As suggested by the commenter, and based on current 6–AM test methods and laboratory results from the NLCP Pilot PT Program, the Department has raised the proposed 6–AM initial test cutoff in Section 3.4 to 4 ng/mL (*i.e.,* the same as proposed in 2004). The same commenter recommended a higher confirmatory test cutoff (3 ng/mL vs. the proposed 2 ng/mL), and noted that their data show that using an opiates cutoff of 30 ng/mL and a 6–AM confirmatory cutoff of 3 ng/mL identifies more positive 6–AM specimens than urine testing. The comparison of 6–AM positivity rates in urine and oral fluid does not support a

change to the proposed confirmatory test cutoff. Studies have shown that 6–AM is statistically more likely to be detected in oral fluid than urine, regardless of the cutoff. [3 4 5] The Department has retained the 2 ng/mL 6–AM confirmatory test cutoff proposed in 2015, primarily for enhanced sensitivity. Studies have shown that 6–AM concentrations between 1 and 3 ng/mL are detected in the study populations. [2 3 6 7]

One commenter agreed with the proposed test cutoffs for phencyclidine (PCP). Three others disagreed, recommending that the Department use the 2004 proposed cutoffs (*i.e.,* 10 ng/mL for both the initial and confirmatory tests). The Department has evaluated the comments and agrees with commenters that there is an insufficient scientific basis to warrant changes from the PCP test cutoffs in the April 13, 2004 proposed Guidelines (69 FR 19673), which are currently used by many test manufacturers and laboratories. Therefore, the Department has raised the proposed cutoffs in Section 3.4 as follows: PCP cutoffs are 10 ng/mL for both the initial and confirmatory tests.

Six commenters disagreed with the proposed test cutoffs for amphetamines. Two of these commenters recommended that the Department use the 2004 proposed cutoffs (*i.e.,* 50 ng/ml for both the initial and confirmatory tests). One recommended that the 2004 cutoff be used for the initial test; another recommended using the 2004 cutoff for the initial test and half of that concentration (25 ng/mL) as the confirmatory test cutoff. One commenter suggested cutoffs of 150 ng/mL or 120 ng/mL. One suggested setting cutoffs at 120 ng/mL or above to reduce the number of unverified positive initial tests. One commenter requested the basis for using different initial and confirmatory test cutoffs for methylenedioxymethamphetamine (MDMA).

The Department has evaluated the comments and agrees with commenters that, for amphetamines, there is an insufficient scientific basis to warrant changes from the initial test cutoffs in the April 13, 2004 proposed Guidelines (69 FR 19673), which are currently used by many test manufacturers and laboratories. Therefore, the Department has raised the proposed initial and confirmatory test cutoffs in Section 3.4 as follows: The initial test cutoff for amphetamines (*i.e.,* amphetamine, methamphetamine, MDMA, and MDA) is 50 ng/mL, and the confirmatory test cutoff for each amphetamine analyte is 25 ng/mL.

Testing for Marijuana Use

The Department requested comments on several topics related to testing for marijuana use. Public comments and the Department's responses are described below. After reviewing the comments, as well as the results of scientific studies published after the development of the proposed OFMG, the Department has decided to test for one marijuana analyte, delta-9-tetrahydrocannabinol (THC). THC is the primary psychoactive constituent (or cannabinoid) of the cannabis plant and is the primary intoxicant in marijuana. After careful consideration of all available evidence for THC in oral fluid, the Department has decided to retain the proposed 4 ng/mL initial test cutoff for THC in the final OFMG. Details regarding this decision are described below.

The Capability of Laboratories To Test Delta-9-Tetrahydrocannabinol-9-Carboxylic Acid (THCA) Analyte Using a Cutoff of 50 pg/mL

One commenter agreed and four commenters disagreed that laboratories were currently capable of testing THCA in oral fluid using this cutoff. One commenter stated that laboratory instrumentation required for the analysis of THCA in oral fluid is widely available and can be added to routine laboratory testing. The commenter listed examples: Two-dimensional gas chromatography/mass spectrometry (GC/MS), GC/MS/MS, and liquid chromatography (LC)/MS/MS. Three commenters disagreed, stating that it would require significant investment in more sensitive instrumentation. One commenter disagreed, stating they doubt the capabilities of the laboratories to consistently test for THCA with accuracy, sensitivity and validity. One commenter disagreed, stating that the number of laboratories with the experience in testing for THCA is limited. The Department has evaluated the comments and agrees that there is a limited number of laboratories currently testing for THCA in oral fluid. Only one commercial drug testing laboratory participating in the Oral Fluid Pilot PT program performed THCA testing. Furthermore, due to the concentration differences between THC (*i.e.,* nanogram/milliliter or ng/mL levels) and THCA (*i.e.,* picogram/milliliter or pg/mL levels), immunoassays do not have sufficient cross-reactivity to enable use of a single assay for both analytes. Initial testing for both THC and THCA would require two separate immunoassay kits or use of alternative technology. No current immunoassay has been identified that is selective for THCA only. Laboratories planning to become HHS-certified to test federal agency oral fluid specimens may already have instrumentation for confirmatory testing that could be used as an alternate technology for initial testing, but may incur additional costs to develop and validate these new initial drug tests.

The Validity of Whether THCA Can Be Established as an Accurate, Sensitive and Valid Marker for Oral Fluid Testing To Detect Marijuana Use and Whether THCA Should Be Used To Extend the Window of Detection for Marijuana Use

Four commenters agreed with THCA as a test analyte. These commenters believe that analysis of THCA may prevent or minimize the risk of positive results due to ''passive exposure'' (*i.e.,* a nonsmoker's exposure to secondhand marijuana smoke). One commenter stated that if both THC and THCA analytes are required to be present to constitute a rule or policy violation, this would also eliminate protracted detection of THCA. The commenter suggested that if only one of the marijuana analytes is reported, it could be addressed as a safety concern. This commenter also opposed MROs requesting THCA testing as needed and, as an alternative, suggested requiring disclosure from the donor at the time of collection (*i.e.,* the collector would ask the donor whether the donor had been exposed to marijuana recently and testing for THCA would be performed based on the donor's answer). If the donor indicated no recent exposure, the donor has waived the right to a passive inhalation defense. One commenter recommended an agency or employer should have the option to choose either test (THC or THCA), providing flexibility for employers' testing goals. One commenter noted that THCA testing, if included in the Guidelines, would be in conjunction with THC testing and expressed concerns including how to handle two test results (THC and THCA) that do not agree, additional costs, longer turnaround time, and handling of retests.

Six commenters disagreed with THCA as a test analyte. One commenter disagreed, suggesting solely testing for the active parent drug is one of the defining characteristics of oral fluid testing. Two commenters disagreed, suggesting THCA is not a reliable metabolite to be an appropriate marker for marijuana use. One commenter disagreed, stating that THCA is only present in oral fluid at very low levels. One commenter disagreed, suggesting that under realistic conditions of casual passive exposure and specimen

collection where the collection occurs outside the exposure area, a donor would not test positive for THC at the currently used initial test (3 ng/mL) and confirmatory test (1.5 ng/mL) cutoffs. One commenter disagreed, stating that more research is needed before adding THCA to the Guidelines. One commenter disagreed, indicating that, for the majority of the time, no significant THC positives are reported for samples containing THCA alone. The commenter also stated that for THCA alone (in the absence of THC) to be detected as positive in the immunoassay, the level must be at least 1,000 pg/ml, and that specimen volume is limited and should not be wasted for unnecessary tests.

The Department has evaluated the comments and decided to use THC as the sole initial and confirmatory test analyte for marijuana, with a 4 ng/mL initial test cutoff and a 2 ng/mL confirmatory test cutoff. This decision is supported by the reasons detailed below.

First, the Department is not aware of any scientific evidence to suggest that individuals would test positive for THC under the standards in these Guidelines as the result of incidental exposure to secondhand marijuana smoke. The preamble to the proposed OFMG, published on May 15, 2015, provided information on THC and THCA results from studies of subjects who were passively exposed to marijuana smoke under a variety of exposure conditions.[8–11] These studies, detailed below, were conducted under conditions of extreme marijuana smoke exposure for several hours in enclosed spaces (*i.e.,* heavy smoke in unventilated and ventilated conditions). The study data indicate that transient amounts of THC may be present in nonsmokers' oral fluid for a few hours (*i.e.,* one to three), but only under those extreme conditions, meaning exposure to smoke from multiple cannabis cigarettes in an enclosed space for an extended time period.

One 2011 study tested nonsmokers in two Dutch coffeehouses where marijuana was being smoked.[10] While some positive tests were obtained from the subjects, those samples were taken during a time of ongoing exposure to marijuana smoke in the coffeehouses, no subjects tested positive after returning for a final collection 12 to 24 hours after exposure. It should be noted that at the time of this notice's publishing, recreational and/or medical marijuana use is not permitted in places of public accommodation under either state or federal law. While this study demonstrated the types of THC oral fluid concentrations that could be obtained during exposure to secondhand marijuana smoke, the study is not directly applicable to Federal drug testing because the positive specimens collected in this study were collected during ongoing exposure to secondhand marijuana smoke, which does not approximate federal drug testing collection conditions.

A more recent study exposed nonsmokers to extreme levels of marijuana smoke under controlled conditions.[12 13] The extreme exposure in this 2015 study consisted of three different one-hour sessions in which nonsmokers were enclosed in a sealed room with six smokers who smoked cannabis cigarettes almost continually through each session. The room was a specially constructed sealed Plexiglas chamber (10 ft. by 13 ft. with a 7-ft. ceiling). Nonsmokers and smokers were seated around a table in alternating seats and the nonsmokers were continually exposed to heavy amounts of marijuana smoke. In two sessions, there was no air flow (*i.e.,* air conditioning was turned off) and in one session, the air conditioning was turned on. Heavy marijuana smoke was present in each session and the smoke caused eye irritation in the two non-ventilated sessions. Because of the extreme smoke conditions, most participants elected to wear eye goggles to reduce eye irritation. In this study, 3 of the 6 nonsmokers were negative directly after the exposure concluded (0 hours) and 4 of 6 were negative at 0.5 hours.

Some of these subjects (nonsmokers) also reported drug effects that were approximately 25% of the smokers' responses (*i.e.,* self-reported effects on a visual analog scale). The nonsmokers also exhibited detectable levels of performance impairment on some behavioral/cognitive assessments. Therefore, a reasonable donor in a safety sensitive position who is aware that he or she is in an enclosed environment with heavy levels of secondhand marijuana smoke should understand that he or she is very likely to experience the effects of inhaled marijuana smoke if he or she remains in this type of environment. Importantly, it is worth noting that exposure to the extreme levels of marijuana smoke in all three study sessions (*i.e.,* non-ventilated and ventilated) does not represent a real-world situation and, therefore, is an unlikely passive exposure situation for donors in a federal agency testing program.

The marijuana studies described above indicate that transient amounts of THC may be present in nonsmokers' oral fluid between one to three hours after prolonged, extreme exposure. Conversely, however, in two similar passive exposure studies from 2001 and 2005, none of the nonsmoking subjects tested positive using cutoffs that were lower than the OFMG THC cutoffs (*i.e.,* 4 ng/mL for initial tests and 2 ng/mL for confirmatory tests).[8 9] While the exposure in the 2005 study was ''extreme,'' both the 2001 and 2005 studies represent more likely ''real world'' situations than the 2015 study.

In the 2005 study of nonsmoking individuals exposed to marijuana smoke in an unventilated passenger van, none of the passively exposed individuals tested positive using a 3 ng/mL initial test cutoff when the oral fluid collection device was protected from exposure to contaminated surfaces.[9] In this two-part study, four non-smoking subjects sat beside four active cannabis smokers who each smoked a single cannabis cigarette containing either a low dose of THC (Study 1) or high dose of THC (Study 2). In Study 1, oral fluid was collected inside the THC-contaminated van. Maximum oral fluid THC concentrations in non-smoking subjects were 7.5 ng/mL but declined to negative levels within 45 minutes of exposure. In Study 2, oral fluid was collected outside the van. Even though the dose of THC was more than twice the dose in Study 1, the maximum concentration detected in the passively exposed subjects was 1.2 ng/mL, which is well below the initial and confirmatory THC cutoffs in these Guidelines. When potential contamination during collection was eliminated in Study 2, all non-smoking subjects were negative at both initial and confirmatory cutoff concentrations throughout the study.

In the 2001 study, subjects were administered a single dose of marijuana by smoked and oral routes, and their oral fluid and urine THC test results were compared.[8] The study used a 1 ng/mL THC initial test cutoff and a 0.5 ng/mL THC confirmatory test cutoff, both lower than the THC cutoffs in these Guidelines (*i.e.,* 4 ng/mL initial test cutoff and 2 ng/mL confirmatory test cutoff). Two nonsmoking subjects were included to simulate passive exposure scenarios (*e.g.,* sitting in an unventilated room where marijuana is smoked). These subjects were positive by immunoassay using the 1 ng/mL initial test cutoff at 1- and 4-hours post-exposure but negative by the confirmatory test using a 0.5 ng/mL cutoff.

These carefully executed studies on passive exposure are considered strong evidence that exposure to secondhand marijuana smoke under normal ventilation conditions presents no risk

that an individual will have a passive exposure related positive test result under the standards used in these Guidelines.

Another reason for the Department's decision to test only for THC is that THCA cannot be reliably detected in all individuals who use marijuana. Two recent studies investigated the presence of THC and THCA in oral fluid after various routes of administration.[15 16] One study characterized marijuana analytes including THC and THCA in oral fluid of nine occasional and 11 frequent marijuana smokers after smoked, vaporized, and oral administration (*i.e.,* ingestion of a brownie containing marijuana).[15] THC was present in oral fluid specimens in all individuals from both groups, after all routes of administration, immediately after use. THC was detected above the OFMG confirmatory cutoff (*i.e.,* 2 ng/mL) for 32 hours with the occasional users and 72 hours with the frequent users. Of the nine occasional users, all tested positive for THC using the OFMG confirmatory cutoff after all administration routes. However, only three occasional users tested positive for THCA (*i.e.,* at or above 15 pg/mL) after all administration routes. In a second study, drug-free subjects ate brownies containing marijuana in three separate dosing sessions, with THC concentrations of 10 mg, 25 mg, and 50 mg.[16] The appearance of THCA in oral fluid in this study was highly variable, and THCA was not present in all subjects. Within the first eight hours after marijuana ingestion, 116 oral fluid specimens were positive for either THC or THCA. Of those specimens, 23 specimens were positive for both THC and THCA, 75 were positive for THC only, and 18 were positive for THCA only. Therefore, THC was detected in approximately 84.5% of the positive oral fluid tests, while THCA was only detected in approximately 35.3%. These studies support the Department's decision to test for THC by showing that THCA cannot be as reliably detected as THC in all marijuana users.

The Department's decision to use THC as the initial and confirmatory test analyte is also supported by the differences between the detection patterns of the two analytes in occasional smokers versus chronic frequent smokers. For example, one study showed that, although THCA was detected in frequent cannabis smokers almost 100% of the time studied, occasional smokers did not consistently test positive for THCA using the previously considered confirmatory test cutoff concentration of 0.05 ng/mL.[17] Some individuals tested negative for THCA after smoking cannabis. Consequently, confirmatory testing for THCA without performing an initial test for THCA would be biased toward detecting chronic frequent cannabis smokers and would be ineffective in detecting occasional users. Such an outcome would diminish the reliability of marijuana testing using oral fluid. It is also important to note that occasional users may exhibit greater acute impairment than chronic frequent users due to the lack of tolerance to cannabis effects.[18] This consideration suggests that an oral fluid drug testing system that relies upon testing for THCA to detect marijuana use may fail to identify occasional users who could pose a safety risk to a federal agency's enterprise.

The Department believes that an immunoassay initial test with the appropriate sensitivity for testing for both THCA and THC could allow oral fluid marijuana tests to take advantage of THCA's extended detection window. The preamble to the proposed OFMG, published on May 15, 2015, noted the lack of scientific data on the time course of excretion or the detection window of THC, THCA, and conjugated THCA in oral fluid following marijuana use, especially for occasional users. It was noted that studies of daily marijuana smokers indicated that THC is detectable for up to two days, but THCA continued to be excreted in oral fluid during abstinence for several weeks in daily users.[19] Two other studies evaluated oral fluid results following cannabis smoking (*i.e.,* one cannabis cigarette containing 6.8% THC).[17 20] In a 2013 study, oral fluid was collected from 10 participants using the Quantisal™ (Immunalysis) oral fluid collection device over a 22-hour period.[17] The authors used a 0.5 ng/mL cutoff for THC and a 7.5 pg/mL cutoff for THCA. The mean time to last concentration and the mean last concentration was 12.3 hours and 5.1 ng/mL for THC and 14.6 hours and 42.3 pg/mL for THCA, thus providing evidence of a longer detection window for THCA. A 2012 study evaluated cannabinoid concentrations in oral fluid of chronic and occasional smokers.[20] Oral fluid was collected 19 hours before smoking to 30 hours after smoking, using the Statsure Saliva Sampler™ (Statsure Diagnostic Systems). The authors concluded that: (1) All specimens were THC positive for up to 13.5 hours post-smoking without significant differences between chronic and occasional smokers, (2) THCA provided longer detection times than THC in the 13.5 to 30 hour post-smoking period in all chronic smokers, and (3) THCA windows of detection for chronic cannabis smokers extended beyond 30 hours.

However, the Department has not identified immunoassay technology that is feasible as an initial test for both THC and THCA in a high-throughput laboratory environment. Such technology is necessary for the implementation of THCA testing in the federal drug testing program because: (1) THCA-only testing is not a viable option for the federal drug testing program (as discussed previously), and (2) even though THCA and THC can be tested during the confirmation phase of drug testing, the theoretical advantages of THCA's longer detection window will not be achieved unless THCA can be detected in the initial test. In other words, in the absence of a viable initial test to detect THCA, specimens positive for THCA only would not advance to confirmation testing. Therefore, until a suitable immunoassay initial test that is capable of screening for both THC and THCA is available, the Department believes that its decision to test for THC using the cutoffs established in these Guidelines provides federal agencies with an efficient, cost-effective and reliable means to detect marijuana use.

As such, it is the conclusion of the Department that a 4 ng/mL initial test cutoff for THC is supported by scientific studies and is consistent with the Department's objective of detecting the use of illicit drugs while, to the extent practicable, eliminating the risk of positive test results caused solely by the drug use of others and not caused by the drug use of the individual being tested, as directed by the SUPPORT for Patients and Communities Act, Public Law 115–271, section 8107(b).[14]

Lowering the Initial Test Cutoff Concentration for THC to Either 2 or 3 ng/mL and Lowering the Confirmation Test Cutoff Concentration for THC to 1 ng/mL To Extend the Window of Detection for Marijuana Use

Three commenters recommended lowering the THC initial test and confirmatory cutoffs to extend the window of detection; one commenter recommended lowering the initial test cutoff for this reason, but keeping the proposed confirmatory cutoff. One commenter recommended a slightly lower confirmatory cutoff (*i.e.,* 1.5 ng/mL). Two commenters agreed with the proposed THC cutoffs.

Two other commenters recommended increasing the initial and confirmatory THC cutoffs, so claims of positive

results due to passive exposure will not be justified.

The Department's decision on initial and confirmatory cutoffs is discussed above, but to reiterate, the Department concluded after careful review of all available scientific evidence that: (1) Credible claims of positive THC tests resulting from second-hand smoke/passive exposure are extremely unlikely, and (2) the only scenario in which there is a theoretical possibility of testing positive for THC as the result of second-hand smoke/passive exposure under these Guidelines involves sustained exposure to extreme levels of marijuana smoke. The Department is confident that under these Guidelines, only a donor's marijuana use would be identified.

Performance Requirements for an Oral Fluid Collection Device

One commenter agreed and one commenter disagreed with requiring the use of only collection devices that have been cleared by the Food and Drug Administration (FDA). One commenter suggested the requirements for collection devices should be developed by appropriate professionals after suitable scientific and stakeholder review, while another suggested the requirements be determined by laboratories and manufacturers. One commenter disagreed with the Guidelines, and suggested that only devices using ''the swab technique'' be required.

The Department has evaluated these comments, and maintained the requirement in Section 7.1 for oral fluid collection devices to be FDA-cleared.

Five commenters addressed proposed volume specifications. Three commenters suggested that the Department specify oral fluid collection and/or diluent volume as a percentage and not a specific volume, due to variability in commercially available devices. One commenter encouraged increasing the allowed specimen and diluent volume variance to +/− 20%. One commenter believes that the proposed 0.05 mL diluent variance is too small and not realistic. One commenter suggested that the Guidelines not specify a required volume, but emphasize that laboratories choose devices that would ensure sufficient volume is collected for initial and confirmatory testing. One commenter disagreed with the proposed variance in specimen collected and suggested that the device must collect a known volume (similar to the ''European Guidelines for Workplace in Oral Fluid''). This commenter also disagreed with the 1 mL collection requirement, stating that LC/MS/MS methods use approximately 200 mcL of oral fluid and that reducing the volume will reduce the time required for collection.

The Department has evaluated these comments, and revised Section 7.3(b) to specify oral fluid collection and diluent volumes as percentages (rather than specific volumes as proposed). The Department agreed with commenters that specifying allowable diluent variance as a percentage rather than volume would allow different manufacturers to produce their oral fluid collection devices with an optimized volume of diluent while ensuring reliability across systems. The Department also changed the specimen volume variance to a percentage for consistency. Section 7.3 specifies variances of 2.5% for diluent volume and 10% for specimen volume, based on information obtained from device manufacturers. The Department also maintained the requirement to collect at least 1 mL of oral fluid. This is a reasonable collection volume that will enable sufficient specimen for testing (*e.g.,* when repeat testing or confirmatory tests for multiple drugs are required).

Four commenters addressed the proposed device requirements for recovery of ≥90% (but no more than 120%) of drug and/or drug metabolite at (or near) the initial test cutoff. The commenters disagreed with the proposed requirement of ≥90%, and suggested recovery between 80% and 120%. One commenter noted that 80% to 120% recovery is consistent with current FDA-cleared systems. One commenter cited adherence of THC to surfaces as a problem in achieving 90% recovery, and recommended either requiring ≥80% for all drugs or requiring ≥80% recovery for THC and ≥90% recovery for other drugs. One commenter agreed with specifying minimum and maximum recovery, and recommended additional emphasis on the consistency of recovery performance of the device and confirmatory methods.

The Department has evaluated these comments, and revised Section 7.3(b) to change the lower limit for drug recovery from ≥90% to ≥80%.

Two commenters addressed stability at room temperature. One commenter agreed with the requirement for stability at room temperature for at least one week, and one commenter disagreed. This commenter indicated that in-house studies found cocaine and 6–AM were unstable for that length of time and also indicated that specimens are typically received at the laboratory one to two days after collection.

The Department has evaluated these comments, and changed the stability requirement in Section 7.3(b) from one week at room temperature to five days at room temperature. Because oral fluid is collected with either a preservative buffer (*i.e.,* collection device with diluent) or preservative dry reagents (*i.e.,* neat oral fluid collection), normal transport conditions are not expected to affect stability of the drugs and/or drug metabolites. The Department will include guidance to collectors concerning proper collection and transport of oral fluid specimens in the Oral Fluid Specimen Collection Handbook.

Medical Review Officer (MRO) Reporting Procedures for Positive Morphine/Codeine Results

In Section 13.5, the Department proposed a concentration of 150 ng/mL for codeine and morphine to be used by the MRO to report a positive result in the absence of a legitimate medical explanation (*i.e.,* prescription), without requiring clinical evidence of illegal use, and to rule out the possibility of a positive result due to consumption of food products. The Department requested comments on the appropriateness of this concentration. One commenter agreed. Six commenters disagreed: One commenter recommended 100–120 ng/mL, one commenter recommended 50–100 ng/mL, one commenter recommended 120 ng/mL, and one commenter recommended 40 ng/mL. One commenter suggested that no additional decision point is needed because, based on scientific studies including in-house studies, positive opiate results using a 40 ng/mL cutoff are not typical and are difficult to achieve, thus there is no justification for an MRO reversal of a codeine or morphine result less than 150 ng/mL. One commenter expressed concern that the 150 ng/mL decision point would not rule out positive codeine/morphine results due to food products and suggested that the Department use a much higher decision point or require clinical evidence of illegal drug use before an MRO verifies any opiate results as positive. Based on evaluation of these comments and examination of the data from scientific studies, the Department has concluded that no change is needed.[21–24] The 150 ng/mL concentration is higher than the highest concentration seen in study subjects at one hour and later after consumption of raw poppy seeds and products containing poppy seeds.

HHS List of FDA-Cleared Oral Fluid Collection Devices

The Department requested comments on whether HHS should publish a list of FDA-cleared oral fluid collection devices. Seven commenters agreed. One commenter disagreed, stating that it is sufficient to provide regulation on requirements and noting that the Department does not publish a list of FDA-cleared urine specimen containers. After further review, the Department has decided not to publish a list. The list might not reflect all current FDA-cleared oral fluid collection devices, and could be misconstrued as a list of SAMHSA-approved devices. Also, FDA clearance does not mean that the collection device meets OFMG requirements. The federal agency and/or the HHS-certified laboratory must ensure that the FDA-cleared device meets the device requirements in Sections 7.2 and 7.3. FDA has a searchable database on its website that can be used to identify FDA-cleared oral fluid collection devices. The Department will include a link to this database on the SAMHSA website *http://www.samhsa.gov/workplace.*

Medical Review Officer (MRO) Requalification—Continuing Education Units (CEUs)

The Department requested comments on requiring MRO requalification continuing education units (CEUs) and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required as part of MRO requalification. Three commenters agreed with requiring MRO recertification, but disagreed with the addition of CEU requirements to the Guidelines. Two commenters disagreed with specifying the number of CEUs required. Two commenters indicated that certification entities already enforce training requirements and recommended that acceptance of CEUs be handled by MRO certification boards, not the Department. Two commenters recommended a requirement of annual CEUs: One suggested 16 CEUs and the other recommended three CEUs. One commenter recommended 12 CEUs prior to initial certification, eight CEUs every five years, and also recommended two CEUs related to the new requirements/topics within two years of implementation of the revised Guidelines. The Department has evaluated the comments and has concluded that requirements for continuing education units will remain with the MRO certification entities and will not be included in the Guidelines. The Department has removed references to MRO training entities in Sections 13.2 and 13.3, because training documentation is maintained by MRO certification entities. The Department agrees with the comment that MROs should receive training on revisions to the Guidelines and has added item Section 13.3(b) to require such training prior to the effective date of revised Guidelines, to ensure that all MROs are trained in program requirements before performing MRO duties for federal agency specimens.

Split Specimen Collection Methods

All federal agency collections are to be split specimen collections. The donor's primary (A) specimen is tested and the split (B) specimen is available for testing if the donor requests a retest at another HHS-certified laboratory. For urine, one specimen is collected from the donor, then the collector pours the collected specimen into two bottles that are then labelled as A and B specimens. Most current oral fluid collection devices collect a single specimen that cannot be divided into A and B specimens. Therefore, the Department requested comments on whether serial or simultaneous collection using two collection devices constitutes a split oral fluid collection, and recommendations for any other oral fluid collection processes that enable subdividing the collected specimen. Three commenters agreed with the proposed guidelines as written. Two cited problems with collecting expectorated oral fluid (*i.e.,* difficult to obtain a sufficient specimen, distasteful to donor and collector), and stated that collection with a device provides analyte stability, a homogenous specimen, and facilitates processing in the laboratory. The commenters noted that the split specimen requirement to identify the presence of the drug addresses any concentration differences between first and second specimens. They also noted that split collections with two devices are currently used for non-regulated testing without issue and that scientific studies support these methods. Five commenters disagreed. Some raised concerns over possible insufficient specimen volume and non-homogenous specimens leading to possible discrepant primary and split specimen results. One commenter disagreed stating that the use of two devices for each collection increases costs. One commenter believes that serial collections using two devices may increase the likelihood of collection problems (*e.g.,* collector forgets to perform the second collection; the donor may leave the collection site or be out of collector's line-of-sight between collections; the two-minute period may be exceeded). The Department has evaluated the comments and has concluded that no change is needed. Either serial or simultaneous collection using two collection devices constitutes a split oral fluid collection for federal workplace drug testing programs. These split collection procedures are described in Section 8.8. The Department revised the split specimen collection definition in Section 1.5 and revised Section 8.8(a) to clarify that the OFMG do not prohibit collection of a single specimen and subdividing the collected specimen into primary (A) and split (B) specimens. In Section 2.5, the Department clarified that the split oral fluid specimen may be collected using two devices or using one device and subdividing the specimen.

Discussion of Sections

The Department has not included a discussion in the preamble of any sections for which public comments were not submitted or where minor typographical or grammatical changes were made.

Subpart A—Applicability

1.5 What do the terms used in these Guidelines mean?

One commenter requested that ''external service provider'' be defined, because this is a new term included in the proposed Guidelines. The Department agrees and has added the definition ''An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or, for urine, an HHS-certified Instrumented Initial Test Facility (IITF).''

Two commenters disagreed with the proposed definition for ''invalid result'' which indicated that an invalid result was reported only when an HHS-certified laboratory could not complete testing or obtain a valid drug test result. The Department agrees and has reinstituted wording from the definition in the Guidelines effective October 1, 2010 (73 FR 71858). The definition in Section 1.5 is ''The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.7 when a positive or negative result cannot be established for a specific drug or specimen validity test.''

To address comments described in this preamble under Section 13.1, the Department deleted the definition for ''non-medical use of a drug.''

Two commenters found the definition of ''specimen'' confusing, because the term ''sample'' used in the definition

was also defined as a representative portion of a donor's specimen. The Department agrees and has reinstituted some wording for the definition of ''specimen'' from the Guidelines effective October 1, 2010 (73 FR 71858) for clarity. The definition in Section 1.5 is ''Fluid or material collected from a donor at the collection site for the purpose of a drug test.''

The Department revised the definition of ''split specimen collection (for oral fluid)'' to clarify that the OFMG allow collection of a single specimen and subdividing the collected specimen into primary (A) and split (B) specimens. This is consistent with the change described in this preamble under Section 8.8(a).

For clarity, the Department added a definition for the term ''undiluted (neat) oral fluid'' which is used throughout the OFMG. The definition in Section 1.5 is ''An oral fluid specimen to which no other solid or liquid has been added. For example, see Section 2.4: a collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.''

1.6 What is an agency required to do to protect employee records?

One commenter suggested that the non-applicability of the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) should be clearly stated in the Guidelines. The Department has evaluated the comment and has concluded that the applicability of HIPAA and other relevant privacy laws is clearly stated in Section 1.6. Accordingly, except for minor rewording for clarity, no further revisions are necessary.

1.7 What is a refusal to take a federally regulated drug test?

The Department proposed within Section 1.7 what is a refusal to take a federally regulated drug test. Two commenters noted that this section does not include the same requirements as Section 1.7(a)(10) of the UrMG defining a refusal to test when a collector finds a device intended for the purpose of adulteration or substitution and recommended adding similar language to the OFMG. The Department has evaluated the comments, and agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting the specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Sections 1.7, 8.3(d), and 8.4(c) accordingly. Collectors will inspect the donor's oral cavity to ensure it is free of items that may impede or interfere with the drug test as described in Section 8.3.

One commenter recommended that OFMG Section 1.7 include the same requirements as UrMG Section 1.7(a)(5) defining a refusal to test when the donor failed to provide a sufficient amount of specimen when directed, ''and the required medical evaluation did not identify a legitimate medical explanation for the failure.'' The Department agrees with this comment and has added a new item 4 to Section 1.7(a) consistent with the UrMG requirement.

One commenter recommended clarification that a donor's refusal to provide a split specimen will also qualify as a refusal to test. The Department has evaluated the comment and has added this as a refusal to test in Sections 1.7(a)(7) and Section 8.5(b). If the donor refuses to provide a split specimen, the collector will report this as a refusal to test.

Also in regard to Section 1.7, one commenter suggested expanding the section to include specific actions that would be classified as a refusal to test. The commenter suggested wording under the current example ''disrupt the collection process'' describing actions specific to OF collections ''(*e.g.,* disrupt the collection process including: biting on the collection device, sucking the fluid back out of the device, failure to open mouth when directed for inspection, failure to rinse mouth when directed, failure to remove foreign object from mouth when instructed, failure to permit the observation or monitoring of the specimen collection, avoiding swabbing in-between teeth and the gum line when instructed, failure to follow the collector's instructions on swab location in the mouth, attempting to conceal chemicals or mints in the mouth, attempting to use a mouth wash immediately prior to or during the collection, attempting to chew ice during the collection, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector, possess or wear a prosthetic or other device that could be used to interfere with the collection process, other failures to comply with the collector's instructions or attempt to defraud the drug test)''.

The Department has evaluated the comment and has added the failure to rinse the mouth when directed by the collector as an example of donor actions classified as a refusal to test in Sections 1.7(a)(7) and in Section 8.3(d)(2). It should be noted that Section 1.7(a)(7) lists some examples. In practice, the trained collector determines whether the donor's action is a refusal to test. Many of the commenter's described actions would disrupt the collection process and thus constitute a refusal to test under Section 1.7(a)(7). The Department will consider the commenter's suggestions during preparation of guidance which will be provided in the HHS Oral Fluid Specimen Collection Handbook.

One commenter noted that the collector does not report a refusal to test when a donor leaves the collection site before the collection process begins for a pre-employment test. The commenter recommended defining the beginning of the pre-employment collection process as the point at which the donor is asked to present photo identification. The Department agrees with the suggestion to define the beginning of the collection process specifically for this situation. However, the Department has designated the beginning as the step described in Section 8.4(a), when the collector provides or the donor selects a specimen collection device. The Department has revised Sections 1.7(a)(2) and (3) to include a reference to this section. All subsequent items in Section 1.7(a) (*i.e.,* items 4—10) apply once the donor has arrived for the pre-employment test collection.

1.8 What are the potential consequences for refusing to take a federally regulated drug test?

The Department reworded Section 1.8(b) to clarify that the requirements in this section apply to donors who fail to appear at the collection site in a reasonable time for any test (except a pre-employment test), as described in Section 1.7(a)(1).

Subpart B—Oral Fluid Specimens

2.1 What type of specimen may be collected?

Ten commenters agreed with adding oral fluid and three commenters disagreed with adding oral fluid and alternate matrices. One commenter raised questions regarding the accuracy of oral fluid testing, MRO interpretation of detection of the parent compound of a prohibited drug, and the cost of oral fluid testing. The Department has evaluated the comments, and believes the concerns raised by the commenters are not sufficient to remove oral fluid testing from the Guidelines. The Department believes that collecting and testing oral fluid specimens according to

the requirements in these Guidelines is an efficient means to detect illicit drug use and ensures that the oral fluid test results are forensically and scientifically supportable.

Numerous commenters expressed concern with the Department's urine collection policy, stating that 7 to 10% of Americans have a condition (''paruresis''), described as a social anxiety disorder which prevents a person from producing urine on demand or in the presence of other people. These commenters stated that if the government wants to seek the largest group of qualified applicants, the Guidelines should specify that a diagnosis of paruresis means non-urine (*i.e.,* oral fluid) testing will automatically be provided, and that donors should not have to attempt to provide a urine specimen first. These comments are not relevant to the OFMG. The OFMG establish the standards and technical requirements for oral fluid testing in federal workplace drug testing programs. Each federal agency will decide whether to collect urine, oral fluid, or both specimen types in their workplace testing programs.

2.2 Under what circumstances may an oral fluid specimen be collected?

One commenter recommended that oral fluid be restricted based on the reason for the test due to the short window of detection compared to urine (and hair), the benefits of observed collection, and the ability to identify the parent or active drug that was used. One commenter recognized the benefit of oral fluid with respect to fewer adulterated, substituted, and/or invalid specimens, but raised concern over the shorter window of detection in oral fluid, especially with respect to pre-employment testing. Two commenters suggested that oral fluid and hair testing be performed for pre-employment and random tests. The Department has evaluated the comments and has concluded that no change is needed. Each federal agency will decide which of the authorized specimen types it will collect and the reasons for collecting each type of specimen.

2.3 How is each oral fluid specimen collected?

One commenter noted that this section does not clearly describe a split specimen ''collected either simultaneously or serially.'' The Department has evaluated the comment and has revised this section to include a reference to Section 8.8, which provides clear descriptions of these split specimen collection methods.

2.4 What volume of oral fluid is collected?

2.5 How is the split oral fluid specimen collected?

Comments on these two sections (*i.e.,* Section 2.4 and Section 2.5) are addressed here. One commenter noted that Sections 2.4 and 2.5 require collection of ''a known volume'' of at least 1 mL undiluted oral fluid, and stated that an absorbent pad device will not meet this requirement. The commenter recommended that these sections be clarified and address all types of oral fluid collection devices. The Department has evaluated the comment and has revised Sections 2.4 and 2.5 to ensure consistent requirements for collection devices with and without a diluent (or other component, process, or method that modifies the volume of the testable specimen). The Department revised Section 2.4 to require A and B tubes to have a volume marking clearly noting a level of 1 mL if the device does not include a diluent (or other component, process, or method that modifies the volume of the testable specimen). This is consistent with requirements in Section 7.3 for devices that modify the volume of the testable specimen to have a volume indicator, to ensure that at least 1 mL of oral fluid is collected. In Section 2.5, in addition to referencing Section 8.8, the Department clarified that the split oral fluid specimen may be collected using two devices or using one device and subdividing the specimen.

Subpart C—Oral Fluid Specimen Tests

3.1 Which tests are conducted on an oral fluid specimen?

One commenter suggested changing the term ''opiates'' to ''opioids'' in the Guidelines. ''Opiates'' is the term used to describe naturally occurring substances known as alkaloids derived from the opium poppy plant (*e.g.,* codeine; morphine; and heroin, which is produced by the acetylation of morphine) that bind to specific receptors in the central nervous system. The broadly used term ''opioids'' includes opiates (*e.g.,* codeine, morphine, and heroin); semi-synthetic compounds (*e.g.,* hydrocodone, hydromorphone, methadone, oxycodone, and oxymorphone); and synthetic compounds (*e.g.,* fentanyl). The Department agrees with the commenter and has changed the term ''opiates'' to ''opioids'' where appropriate to refer to oxycodone, oxymorphone, hydrocodone, and hydromorphone in addition to codeine, morphine, and 6-acetylmorphine (6–AM).

In addition, as described under *Requirements for specimen validity testing* in this preamble, the Department revised Section 3.1 to allow, but not require, oral fluid specimen validity testing.

3.2 May a specimen be tested for additional drugs?

The Department reworded Section 3.2(a) to clarify the additional drug tests that may be performed on federal employee specimens.

3.3 May any of the specimens be used for other purposes?

It should be noted that, consistent with the Urine Mandatory Guidelines, Section 3.3 specifically prohibits conducting, among other types of testing, deoxyribonucleic acid (DNA) testing, on oral fluid specimens unless authorized in accordance with applicable federal law.

3.4 What are the drug test cutoff concentrations for undiluted (neat) oral fluid?

Comments concerning marijuana test cutoffs are addressed under the *Testing for Marijuana Use* section above. Comments on other drug test cutoffs are addressed under *Proposed cutoff concentrations.* To summarize, the Department revised Section 3.4 to use higher cutoffs for some drugs (*i.e.,* initial test cutoffs for 6–AM, PCP, and amphetamines; confirmatory test cutoffs for PCP and amphetamines) than in the proposed OFMG. Other comments related to Section 3.4 are addressed below.

Three commenters disagreed with testing for cocaine in oral fluid, stating that cocaine is not stable in oral fluid, especially at the pH of human oral fluid. The commenters noted that cocaine has a short half-life and hydrolyzes to benzoylecgonine, and that benzoylecgonine is present longer and at higher levels. Two of these commenters further noted that the current industry standard is to test for benzoylecgonine only in oral fluid. One stated that their in-house studies found that testing cocaine did not increase the positivity rate compared to testing only benzoylecgonine. The other commenter refuted the study cited in the preamble to the proposed OFMG that supported the inclusion of cocaine as a test analyte. The Department based the proposed analytes for each drug on the recommendations of a technical workgroup consisting of subject matter experts and representatives from various stakeholder groups (*e.g.,* collection

device and test kit manufacturers, oral fluid drug testing laboratories). In the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, page 28063), the Department included the scientific basis for including both analytes. The inclusion of both cocaine and benzoylecgonine as test analytes will increase the number of specimens that are identified as containing these cocaine analytes and, thereby, will increase the deterrent effect of the program and improve identification of employees using this drug.

One commenter disagreed with testing for hydromorphone and oxymorphone in oral fluid due to extremely low incidence and recommended testing for more prevalent metabolites. The Department has evaluated the comment and decided that no change is needed. Information provided by initial test manufacturers indicates that the proposed analytes (*i.e.,* parent drugs) are present in higher concentrations and in the absence of their metabolites.

One commenter recommended specifying D-isomers as the initial test analytes for amphetamines. The Department agrees that an antibody that is directed toward D-enantiomers in an immunoassay method should be preferred over an antibody that is non-stereoselective, but concluded that no change is needed. The wording in this section is consistent with the UrMG, and the selection of an immunoassay kit or methodology will remain the testing laboratory's choice.

An HHS-certified laboratory may group analytes for initial testing. For clarity, the Department has defined the term ''grouped analytes'' where used in footnote 1 of the table in Section 3.4: ''(*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff).''

The Department proposed criteria for calibrating initial tests for grouped analytes such as opioids and amphetamines, specifying the minimum cross-reactivity to the other analyte(s) within the group. The Department also proposed including methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) as initial test analytes. Four commenters stated that 80% cross-reactivity may not be possible with current immunoassay technology, so may require independent analyses (*e.g.,* hydrocodone and hydromorphone for an opiate assay; MDEA for an amphetamines assay). Two of these commenters noted concerns with additional oral fluid specimen volume needed for the independent assays. Another commenter stated that cross-reactivity specifications for hydromorphone are not necessary, based on their non-regulated testing results (*i.e.,* confirmatory test concentrations detected after using an immunoassay with 60% cross-reactivity for hydromorphone).

The Department has evaluated these comments and concluded that no change is needed for immunoassay cross-reactivity requirements. The cross-reactivity requirements in Section 3.4 are necessary to ensure consistency in testing among laboratories using different immunoassay kits, as well as those using different test methods for initial drug testing. Cross-reactivity must be demonstrated and documented by the manufacturer (*e.g.,* package insert) and by the HHS-certified laboratory (*i.e.,* assay validation studies, reagent lot verification, and batch quality control for any analyte that exhibits less than 100% cross-reactivity).

One commenter stated that the low prevalence of MDA and MDEA does not warrant the burden placed on immunoassay manufacturers and laboratories. The Department has evaluated the comment and has removed MDEA from the Guidelines (*i.e.,* MDEA is no longer included as an authorized drug in Section 3.4). The number of positive MDEA specimens reported by HHS-certified urine laboratories (*i.e.,* information provided to the Department through the NLCP) does not support testing all specimens for MDEA in federal workplace drug testing programs. Because MDEA is a Schedule I drug, a federal agency may test specimens for MDEA in accordance with Section 3.2 (*i.e.,* on a case-by-case basis for reasonable suspicion or post-accident testing, routinely with a waiver from the Secretary). The Department understands that some other analytes have a low incidence, but believes that continued testing for these analytes is warranted in a deterrent program. In particular, inclusion of MDA as an initial and confirmatory test analyte is warranted because, in addition to being a drug of abuse, it is a metabolite of MDEA and MDMA.

Also in Section 3.4, the Department did not specify the target analyte to be used to calibrate an initial test for grouped analytes such as amphetamines or opioids. Three commenters noted that when an immunoassay is calibrated with a low-reacting drug, other analytes may exhibit high cross-reactivity, leading to false initial test positives. Two of these commenters also noted that this may result in possibly different cross-reactivity profiles for some structurally unrelated and concomitantly used prescription and/or over the counter drugs. It was not the Department's intent for the laboratory to calibrate an immunoassay test using an analyte other than that specified by the manufacturer. In the preamble to the proposed OFMG, the Department described using a control containing the lowest reacting analyte at its cutoff concentration to establish the decision point (*i.e.,* when an immunoassay for grouped analytes did not demonstrate at least 80% cross-reactivity to each analyte). The Department has determined that this approach is not necessary, and will not be permitted. There are current immunoassays that meet the requirements of this section for two or more analytes in a group (*i.e.,* analytes in the same drug class that have the same initial test cutoff). As indicated in Section 3.4, the laboratory may use multiple test kits or a single kit to meet the requirements.

However, the Department has revised Section 3.4 regarding the use of alternate technology initial tests for THC and 6-AM. To ensure consistent treatment of specimens, depending on the technology, the confirmatory test cutoff (*i.e.,* 2 ng/mL) must be used for THC and 6-AM. For example, because immunoassays cross-react with various marijuana constituents and metabolites, a specimen that is positive using a cutoff of 4 ng/mL for an immunoassay may not test positive using an alternate technology initial test with a 4 ng/mL cutoff for THC. When using an alternate technology initial test (*e.g.,* LC/MS/MS) that is specific for the target analyte, THC, must be tested using the confirmatory test cutoff.

3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

One commenter recommended that HHS maintain a list of allowable additional tests and reporting criteria (*e.g.,* threshold for reporting as positive, adulterated, substituted, and/or invalid, and a limit of detection as appropriate), to ensure consistency among laboratories and within the testing program. The Department has evaluated the comment and has concluded that no change is needed. The Department does not want to limit the analytes that may be tested, and will provide guidance to laboratories as necessary. It is also noted that the section requires all tests to meet appropriate validation and quality control requirements. The procedures and specimen records for such tests will be reviewed at NLCP inspections. The Department will continue to maintain a

list of HHS-certified laboratories that choose to perform additional tests for regulated specimens. The Department has reworded Section 3.5 in concert with revisions to Section 3.1 removing the requirement for albumin or IgG testing, as described under *Requirements for specimen validity testing* in this preamble.

One commenter asked whether an MRO could submit a blanket request to perform additional testing (*e.g.,* additional opioid metabolites) for all confirmatory specimens (*i.e.,* would laboratories be permitted to monitor the additional compounds in all confirmatory test assays?). The Department believes that testing all specimens for additional analytes may not be appropriate for some tests, especially hydrocodone, hydromorphone, oxycodone and oxymorphone. Recent studies show that testing for norhydrocodone and/or noroxycodone is not necessary for the interpretation of all results.[26 27] Norhydrocodone and noroxycodone metabolites may be helpful for the MRO to interpret test results only when a donor's prescription does not support the test results. The presence of norhydrocodone metabolite would support the use of hydrocodone and validate the donor's prescription. The same could be said for interpreting test results following an oxycodone dose. The presence of noroxycodone metabolite would support the use of oxycodone and validate the donor's prescription. The Department will provide guidance on these and other additional tests that may provide useful information for the MRO in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs. The Department has revised Section 3.5 to clarify that HHS-certified laboratories are authorized to perform additional tests upon MRO request on a case-by-case basis, but are not authorized to routinely perform such tests without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. The Department will continue to allow HHS-certified laboratories to test for D,L amphetamine and methamphetamine routinely or upon MRO request. The Department will provide guidance on these and other additional tests that may provide useful information for the MRO (*e.g.,* tetrahydrocannabivarin) in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs.

Additional drug and specimen validity testing under Section 3.5 does not include DNA testing.

3.7 What criteria are used to report an invalid result for an oral fluid specimen?

One commenter disagreed and recommended deleting Sections 3.7(a-c) and 3.7(g) from the Guidelines due to observed collections by trained collectors. As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Section 3.7 has been revised accordingly.

Subpart D—Collectors

4.1 Who may collect a specimen?

One commenter questioned why the Department prohibits supervisors or hiring officials from collecting oral fluid specimens (unless no other collector is available). The commenter cited fewer privacy concerns in collecting oral fluid versus urine, and indicated that having supervisors collect specimens would be particularly useful in remote locations and/or for post-accident tests. The Department has evaluated the comments and has concluded that no change is needed. The Department will continue to prohibit routine collections by a supervisor, to avoid potential conflicts of interest due to the employee-supervisor relationship as much as possible. The Guidelines permit collections by a supervisor who has been trained as a collector when no other trained collector is available.

4.2 Who may not collect a specimen?

One commenter expressed concern that this section as written may unintentionally prevent the use of valid collection methods (*i.e.,* preventing the donor from collecting their own specimen may prohibit the donor from holding the collection device). The Department has evaluated the comments and has concluded that no change is needed to Section 4.2, which includes general language concerning the entire collection process. Section 8.4 describes steps the collector takes before the donor provides the oral fluid specimen, including reviewing with the donor the manufacturer's instructions for oral fluid collection using the specimen collection device. Section 8.5 describes the collection procedure, including the requirement for the donor to position the device for collection, and for the collector and donor to complete the collection in accordance with the manufacturer's instructions for the collection device. However, the Department has revised the wording in Section 8.5(a)(1) to address all types of oral fluid collection devices allowed by the OFMG (*i.e.,* including those that are not placed in the mouth).

Subpart E—Collection Sites

5.2 What are the requirements for a collection site?

One commenter suggested that the Department require restricted access only to be applicable during a collection period, and allow supplies and records to be stored in nearby secured areas. The Department has evaluated the comments and has concluded that no change is needed. The section clearly describes the requirements and addresses the commenter's concerns.

Subpart F—Federal Drug Testing Custody and Control Form (CCF)

6.1 What federal form is used to document custody and control?

6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

Comments on these two sections (Sections 6.1 and 6.2) are addressed here. Three commenters recommended that the Federal Custody and Control Form (CCF) be revised to address oral fluid specimens. The Department will revise the Federal CCF when Guidelines allowing oral fluid become effective.

The Department reworded items 6.2(b) and (c) for clarity.

Subpart G—Oral Fluid Specimen Collection Devices

7.3 What are the minimum performance requirements for a collection device?

The Department reworded Section 7.3(a) in reference to oral fluid collection volume, as described under Sections 2.4 and 2.5 above, and revised Section 7.3(b) in response to public comments, as described under *Performance requirements for an oral fluid collection device* above.

Subpart H—Oral Fluid Specimen Collection Procedure

8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?

One commenter stated that this section requires the collector to deter adulteration or substitution at the collection site, but does not provide any information on how this is to be done. The commenter recommended that Section 8.2 be deleted or, alternatively, that additional information be added to the section. The Department has

evaluated the comments and has concluded that no change is needed. The section provides the general requirement; the Department will provide more specific guidance as needed in the HHS Oral Fluid Specimen Collection Handbook, which will be issued after these Guidelines become effective.

8.3 What are the preliminary steps in the oral fluid specimen collection procedure?

In response to comments described under Sections 1.7 and 8.4 in this preamble, the Department revised Section 8.3(d) to require the collector to report a refusal to test when a donor brings materials for adulterating, substituting, or diluting a specimen to the collection site.

One commenter requested that the Guidelines clarify (possibly using a flowchart) the different waiting periods in Sections 8.3 and 8.6 (*i.e.,* if multiple waiting periods are required, do they run concurrently or consecutively?). The Department has evaluated the comments and has concluded that no change is needed. The Department will consider the commenter's suggestion during preparation of the HHS Oral Fluid Specimen Collection Handbook.

Several comments concerned Section 8.3 collection procedures regarding rinsing or drinking. One commenter disagreed with the requirement to have tobacco users rinse their mouth prior to an oral fluid collection, noting it is an inconvenience for the collector to provide a place for the donor to spit out the liquid. One commenter requested clarification on oral fluid collection procedures for tobacco users (*e.g.,* is the collector required to ask, is it a refusal if a tobacco user doesn't rinse their mouth, is the donor required to rinse with water, what if the donor uses more than 4 oz. of liquid to rinse?). The Department removed the reference to tobacco users in 8.3(d)(2) because there is no need for all tobacco users to rinse their mouths. The proposed procedure for tobacco users was due to the dark brown color of tobacco juice. The issue is that any discoloration may interfere with initial testing (*i.e.,* not just tobacco juice). The Department reworded this section to include abnormally colored saliva as a reason for the collector to give water to the donor for rinsing their mouth.

One commenter recommended that the Guidelines clarify that if the donor drinks water, the water must not be provided by the donor. For clarity, the Department revised Section 8.3(d)(2) to require the collector to give the donor water (for example, up to 4 oz.) to rinse the donor's mouth when the collector's inspection of the oral cavity identifies any items that could impede or interfere with the collection of an oral fluid specimen. If the donor refuses to rinse, this is a refusal to test. Rinsing with more than 4 oz. of water does not invalidate the collection, so this amount was given as an example rather than a requirement.

One commenter indicated that some collection devices specifically instruct against offering the donor anything to rinse with or drink. This commenter suggested modifying Section 8.3 to make offering of water conditionally allowed, depending on the collection device manufacturer's instructions. The Department has evaluated these comments and concluded that no change is needed. The Department believes that rinsing the oral cavity with water prior to a 10-minute wait period is a reasonable part of the oral fluid collection protocol. The wait period is sufficient to comply with the device instructions, and will not dilute the collected oral fluid.

Several comments concerned Section 8.3 collection procedures regarding inspection of the donor's mouth. One commenter requested clarification on what items need to be removed from a donor's mouth prior to an oral fluid collection (tobacco, food, gum, or mints versus retainers and piercings). One commenter requested clarification of whether ''dental retainer'' refers to a temporary or permanent device (or both), should the device be removed and, if so, where the device should be placed during the oral fluid collection. The Department has evaluated the comments and concluded that only one change is needed: Removal of ''dental retainer'' from the examples of items that must be removed based on a collector's inspection of the donor's mouth in Section 8.3(d). A donor is not required to remove dental appliances such as a retainer. The Department will provide additional information in the Oral Fluid Specimen Collection Handbook to clarify items that may impede or interfere with the collection.

One commenter recommended that the Guidelines address the situation where a donor may have a medical condition that prevents them from opening their mouth for the collector to inspect. The Department agrees with the commenter and has revised Section 8.3(d) to address this situation. The collector will proceed with the same steps as when a donor is unable to provide an oral fluid specimen, as described in Section 8.6(b)(2), and the MRO will follow the steps in Section 13.6(b) requiring a medical evaluation of the donor.

8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

Two commenters believe that if the collector finds an adulterant or substitution product, this should be a refusal to test. As noted under Sections 1.7 and 8.3 in this preamble, the Department agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting a specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Section 8.4(c) accordingly.

The Department deleted Section 8.4(b)(1) for consistency with Section 8.6(b). The deleted item stated that the collector may set ''a reasonable time for a collection based on the device used, not to exceed 15 minutes.'' Section 8.6(b) states that the donor demonstrates their inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?

One commenter suggested that the section should state that the collector be present and maintain visual contact with the donor and collection device during the procedures outlined in this section. The Department has evaluated the comment and has concluded that no change is needed: Sections 8.4(a) and 8.5(a) clearly require the collector to keep the unwrapped collection devices and the donor in view at all times during the collection.

One commenter asked if there was a limit to the number of times a collection could be restarted due to collection device failures. The Department has evaluated the comment and has reworded Section 8.5 for clarity. Section 8.5(a)(1) was revised to indicate that a failure to provide a specimen (which may or may not be due to device failure) prompts recollection using a new device and that the collector documents the failed collection attempt on the Federal CCF. The Department also reworded Section 8.5(b) to clarify that a donor's refusal to begin the collection process after a failure to collect the specimen is a refusal to test. The Department did not set a limit for the number of attempts because there may be different reasons for failing to collect the specimen from the donor. However, the Department

revised the section to require the collector to follow the procedure in Section 8.6 ''after multiple attempts to collect the specimen.''

One commenter stated that HHS should clarify that a donor's refusal to provide a split specimen will also qualify as a refusal to test. The Department agrees with the comment and has revised Section 8.5(b) to include the refusal to provide a split oral fluid specimen as a refusal to test.

Additionally, as described under Section 4.2 above, the Department revised Section 8.5(a)(1) to address all types of collection devices allowed by the OFMG (including those that are not placed in the mouth).

8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

Three commenters disagreed with the requirement for the collector to contact the agency representative for authorization to collect an alternate specimen each time a donor is unable to provide a sufficient volume. These commenters suggested that the Guidelines allow this to be addressed in established standard protocols for the agency. The Department agrees with the commenters. Each federal agency may decide whether to require notification in each case or whether to provide a standard protocol for collectors to follow. Section 8.6 has been revised accordingly.

Also in regard to Section 8.6, one commenter requested additional information on donor hydration during an oral fluid specimen collection (*i.e.,* asking if there is evidence that hydration improves the ability to provide a specimen and whether hydration dilutes the specimen). One commenter indicated that the volume of oral fluid collected does not appear to be directly related to fluid intake and suggested that, because some donors may not be able to provide a sufficient specimen even after the one hour wait time, a urine specimen should be collected immediately. One commenter disagreed with the one hour period allowed for an oral fluid collection, and indicated that there is no evidence provided that dry mouth is eliminated by waiting one hour. The commenter indicated that this extra time allotted costs the employer unnecessary time and money, and maintained that a waiting period of 10 minutes after consumption of 8 oz. of water is sufficient. The Department has evaluated the comments and concluded that no change is needed to Section 8.6. The proposed procedure sets a reasonable time limit within which most donors would be able to provide an acceptable specimen volume (*i.e.,* 10 minutes between attempts to provide the oral fluid specimen, up to one hour), and the section clearly states that the donor is not required to drink any fluids during the wait time. The Guidelines clearly describe the limited circumstances in which the collector offers the donor fluids. However, the Department has revised Section 8.8(a)(2) to expressly prohibit rinsing or drinking between the collection of the primary and split specimens when serially collected.

8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?

One commenter disagreed with the Guidelines as written and suggested that when a donor cannot provide the primary specimen type, an alternate specimen should be collected immediately. The commenter cited the additional time and cost as well as the fact that the collector may not know the agency's policy on alternate specimen types. The Department has concluded that no change is needed for Section 8.7 in response to this comment. The Guidelines will continue to require that the donor be allowed reasonable attempts to provide an oral fluid specimen as described in Sections 8.5 and 8.6. The Department has revised Section 8.6 to allow a federal agency to either require notification in each case or provide a standard protocol for collectors to follow when the donor is unable to provide an oral fluid specimen. The Department has reworded this section to state ''Yes, if. . .'' rather than ''No, unless. . .'' in response to a federal agency's comment and to enhance clarity. The meaning of this section remains the same.

8.8 How does the collector prepare the oral fluid specimens?

One commenter requested clarification of the ''simultaneous'' oral fluid collections. The Department has evaluated the comment and has concluded that no change is needed. Section 8.8(a)(1) describes ''Two specimens collected simultaneously with two separate collection devices.''

One commenter expressed concern that the requirement for a serial collection of a split specimen to begin within two minutes of the first collection may be difficult to monitor and may lead to differences between the two specimens. This commenter requested clarification on how this process will be monitored. One commenter agreed with the two-minute maximum time between serial collections of a split specimen. The Department has evaluated the comments and agrees with the second commenter that no change is needed. The proposed procedure in Section 8.8 sets a reasonable time within which the collector can take the first collection device from the donor and record the time on the Federal CCF, while the donor positions the second device for the collection. Because the collector works with one donor at a time, the collector should have no difficulty monitoring the time between primary and split collections. Furthermore, the Department believes this timing would not affect results of the primary and split oral fluid specimens.

One commenter disagreed with the proposed two-minute maximum time between serial collections of a split specimen and suggested that the time be increased to 10 minutes (so as not to rush the collector in completing chain of custody forms). This commenter suggested that a second specimen should only be collected after an initial test result is obtained (which the commenter indicates can usually be done in 10 minutes). The Department has evaluated the comments and has concluded that no change is needed. The collector is not required to complete the Federal CCF until both the primary and split specimens have been collected. Point of collection testing is not allowed under these Guidelines. That is, all testing must be performed at an HHS-certified test facility.

One commenter asked whether hydration would be allowed between serial split collections. The Department revised Section 8.8(a)(2) to expressly prohibit rinsing or drinking between the collection of the primary and split specimens when serially collected. Prohibiting rinsing or drinking will better ensure consistency of the primary and split specimens.

The Department added an additional item under Section 8.8(a) to clarify that the OFMG allow collection of a single specimen and subdividing the collected specimen into primary (A) and split (B) specimens. A similar change was made to the definition of ''split specimen collection (for oral fluid)'' in Section 1.5.

The Department also removed the word ''known'' in Section 8.8(b) in reference to oral fluid collection volume, as described under Sections 2.4 and 2.5 above.

In response to a federal agency comment, the Department deleted a sentence in item 8.8(h) that required the collector to send a copy of the Federal CCF to the HHS-certified laboratory. The Department agreed with the federal

agency that this instruction is redundant because item 8.8(g) instructs the collector to distribute copies of the Federal CCF as required.

Subpart I—HHS-Certification of Laboratories

9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

One commenter noted that, because proposed initial test requirements allow calibration with a low-reacting analyte, PT schemes would likely need to be designed based on the specific implementation at each laboratory. The commenter provided an example: When an immunoassay is calibrated with a drug/metabolite that exhibits 50% cross-reactivity, the intended target analyte (''calibrant'') at the cutoff concentration would elicit a response well in excess of the cutoff. This could result in inaccurate initial test results (*i.e.,* a positive initial test result for a specimen containing the calibrant at a concentration below the cutoff). The commenter stated that this result could be scored as a ''false positive'' PT result. The Department has evaluated the comment and has concluded that no change is needed. As noted above regarding Section 3.4, it was not the Department's intent for the laboratory to calibrate an immunoassay test using an analyte other than that specified by the manufacturer. NLCP PT schemes are designed based on known cross-reactivity profiles of the initial tests used by HHS-certified laboratories.

Also in regard to proposed Section 9.5, one commenter suggested that the Guidelines use the same wording as in the Guidelines effective October 1, 2010 (73 FR 71858) for retest PT sample specifications (*i.e.,* ''. . . may be as low as . . .'' rather than the proposed wording ''. . . may be less than . . .''). The Department agrees and has reinstituted wording from Section 9.3 of the Guidelines effective October 1, 2010 (73 FR 71858) into Section 9.5(a)(1)(ii).

As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Section 9.5 has been revised accordingly.

9.6 What are the PT requirements for an applicant laboratory?

9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?

Comments on these two sections (Sections 9.6 and 9.7) are addressed here. As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Sections 9.6 and 9.7 have been revised accordingly.

Subpart J—Blind Samples Submitted by an Agency

10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?

Two commenters disagreed with the proposed limit to the number of blind samples required (*i.e.,* a maximum of 400 blind samples per year) in Section 10.1(b). The commenters indicated that for a large agency, there is a very large difference between 3% and 400 samples and suggested keeping only the 3% requirement. Another commenter disagreed with the 3% requirement for blind samples and requested that the amount to be lowered to 1% to lessen the burden on employers. The Department has evaluated the comments and has concluded that no change is needed. The 400 sample limit was added to reduce the burden on large agencies based on the Department's review of agencies' blind testing programs.

One commenter suggested that the wording be modified to clarify that employers are responsible for ensuring blind samples are sent to the laboratories, but that collectors are tasked with submitting the blind samples. The Department has evaluated the comment and has concluded that no change is needed. The wording in Section 10.1(a) clearly describes the responsibilities of the federal agency and the role of the collector in blind sample submission; however, the Department reworded Section 10.3(a) for clarity as described below.

10.3 How is a blind sample submitted to an HHS-certified laboratory?

The Department has reworded Section 10.3(a) to clarify that the collector sends a blind sample to a laboratory as a split specimen (*i.e.,* specimens A and B).

Subpart K—Laboratory

11.9 What are the requirements for an initial drug test?

One commenter noted that HHS previously required initial and confirmatory testing using different techniques, and asked whether this requirement had been removed with allowance of technologies other than immunoassay for initial testing. The commenter expressed concern that an error in the initial drug test could be repeated in the confirmatory drug test using the same method. The Department has evaluated the comment and has concluded that no change is needed. The Guidelines maintain the requirement for initial and confirmatory tests on two separate aliquots to report a result other than negative. The NLCP will review validation and quality control records, as well as specimen records, to ensure that the initial and confirmatory testing methods meet Guidelines requirements and provide scientifically and forensically supportable results.

11.10 What must an HHS-certified laboratory do to validate an initial drug test?

One commenter noted that Section 11.10 provides general information on validation requirements, and asked where detailed requirements can be found. The Department has evaluated the comment and has concluded that no change is needed. The Department will continue to provide details for applicant and certified test facilities through the NLCP.

One commenter asked whether the requirement in 11.10(c) for periodic verification of ''each initial drug test using an alternate technology'' applied to immunoassay tests used differently than originally cleared by the FDA or other laboratory developed tests. The Department has evaluated the comment and has concluded that no change is needed. This section clearly distinguishes initial tests using immunoassay from those using an alternate technology. Furthermore, Section 1.5 includes the definition for ''alternate technology initial drug test.''

11.11 What are the batch quality control requirements when conducting an initial drug test?

Seven commenters disagreed with the requirement for an initial test control targeted at 25% above the cutoff. The commenters noted that drug concentrations are much lower in oral fluid than in urine, and stated that assays are unlikely to perform robustly with current immunoassay technology. One commenter also noted that oral fluid is diluted three- to four-fold. One commenter suggested requiring a control targeted at 50% above the cutoff, consistent with current FDA-cleared assays. The Department has evaluated the comments and has concluded that no change is needed. Consistent with the urine program requirements, laboratories must have the ability to apply the program cutoffs to regulated specimens, and document that ability by analyzing a control targeted at 25% above the cutoff in each batch.

One commenter asked whether the inclusion of ''additional compounds as target analytes'' for amphetamine and

opioid assays affect quality control content requirements. The Department has evaluated the comment and has concluded that no change is needed. The initial drug test quality control requirements in the Guidelines apply to each analyte used to calibrate the test (*i.e.,* immunoassay or alternate technology initial drug test). When a single immunoassay test is used for two or more analytes in a drug class, the HHS-certified laboratory must include a control in accordance with item 11.11(a)(2) for each analyte that has less than 100% cross-reactivity with the assay, to demonstrate that the requirement for at least 80% cross-reactivity has been met.

11.14 What are the batch quality control requirements when conducting a confirmatory drug test?

One commenter stated that analyzing quality control samples with concentrations of a drug or metabolite targeted at less than 40% of the proposed cutoffs would be an analytical challenge for high volume laboratories utilizing GC/MS or LC/MS/MS. The Department has evaluated the comments and has concluded that no change is needed. The NLCP Pilot PT Program has documented the capability of laboratories to meet the proposed OFMG requirements.

Also in regard to the proposed quality control requirements for an initial drug test in Section 11.11 and for a confirmatory drug test in Section 11.14, one commenter requested clarification for the requirement for a drug-free control (*i.e.,* whether the control should contain no drug or whether the control should not contain the specific analyte for that test). The Department has evaluated the comment and has concluded that no change is needed. These Guidelines sections list the requirement for ''at least one control certified to contain no drug or drug metabolite,'' meaning that the control must contain no regulated drug analytes.

11.15 What are the analytical and quality control requirements for conducting specimen validity tests?

The Department has reworded Section 11.15(a) for clarity, to correctly reflect requirements.

11.17 What are the requirements for an HHS-certified laboratory to report a test result?

One commenter suggested that the Department remove the requirement for an executed CCF as the official report for ''non-negative'' specimens and permit the use of an electronic report with the required information. The Department has evaluated the comment and has concluded that no change is needed. The Federal CCF establishes the chain of custody for the specimen from the time of collection until receipt by the laboratory and also contains the certification statement signed by the certifying scientist. The Federal CCF may be paper or electronic.

As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Section 11.17 has been revised accordingly.

11.21 What HHS-certified laboratory information is available to a federal agency?

As described under *Requirements for specimen validity* testing in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. The list of items provided in a standard documentation package for an oral fluid specimen has been revised accordingly [*i.e.,* Section 11.21(b)(4)].

11.22 What HHS-certified laboratory information is available to a federal employee?

One commenter asked why the proposed Guidelines include a requirement for a copy of the semiannual statistical summary report to be sent to the Secretary or designated HHS representative. The Department included the requirement to facilitate compilation of statistical information for the federal drug-free workplace program. This will not place an additional burden on the laboratory other than transmission of the report. The Department will continue to evaluate the effectiveness of this requirement.

Subpart L—Instrumented Initial Test Facility (IITF)

12.1 May an IITF test oral fluid specimens for a federal agency's workplace drug testing program?

One commenter disagreed with prohibiting IITFs for oral fluid. This commenter considers the current HHS-certified urine IITF to be a success in Canada and stated that prohibiting oral fluid IITFs would result in less enthusiasm for regulated procedures and impact workplace safety. At this time, as stated in the preamble to the proposed OFMG, IITFs are not practical and will not be allowed due primarily to the limited specimen volume of oral fluid collected from the donor. The Department will continue to monitor developments in oral fluid drug testing after this new specimen type has been implemented in federal workplace programs, and may reassess the feasibility of allowing IITFs for oral fluid in the future.

Subpart M—Medical Review Officer (MRO)

13.1 Who may serve as an MRO?

Three commenters disagreed with the term ''nonmedical use of a drug'' used in Section 13.1 (and defined in Section 1.5) and indicated that the term changes the role of an MRO from review, verify and ''report a non-negative result'' to review, verify and ''interpret before reporting a result as negative or nonmedical use of a drug.'' Two commenters disagreed with use of ''interpretation of results'' to supplant ''alternative medical explanation.'' One commenter noted that this perceived change in the MRO's role represents an unjustified shifting of risk to the MRO. One commenter believes the term presents a possible legal flaw to Guidelines, stating that this term is legally different from ''safety concern'' and places MROs in the position of being in conflict with the prescribing physician and subject to lawsuits. This commenter stated that even a lack of a finding of nonmedical use could be an issue if the donor subsequently had an accident after using the drug. The same commenter submitted five recommendations related to inclusion of prescription drugs in federal workplace drug testing programs, to address the commenter's concerns with the proposed Guidelines. These five specific recommendations pertain to matters that are outside the scope of these Guidelines, and therefore are not addressed in the Department's response below.

The responsibilities of an MRO to interpret results have largely remained the same between the Guidelines effective October 1, 2010 (73 FR 71858) and these Guidelines. As stated in Section 13.5(c) of these Guidelines, ''if the donor provides a legitimate medical explanation (*e.g.,* a valid prescription) for the positive result, the MRO reports the test result as negative to the agency.'' Accordingly, the intent of the Guidelines, in this context, is to confirm whether a positive drug test is the result of drug use under a valid prescription. Furthermore, the term ''alternate medical explanation'' has never been used in the Guidelines, but has been used in the HHS Medical Review Officer Manual for Federal Workplace Drug Testing Programs.

For the reasons above, the Department believes that the definition of ''nonmedical use of a drug'' and the requirement for a physician serving as an MRO to have knowledge of this topic do not fundamentally change the MRO's responsibilities. However, to address the commenters' concerns, the Department has removed this term from the Guidelines (*i.e.,* revised Sections 1.5 and 13.1).

One commenter requested clarification that it is the federal agency's burden to ensure that the MRO is certified. One commenter asked how the laboratory will be informed that an MRO has met requirements for re-qualification. The Department evaluated the comments and concluded that no change is needed. The MRO is an employee or a contractor of the agency. Therefore, it is the agency's responsibility to ensure that the MRO meets the Guidelines qualification requirements.

Two commenters disagreed with the requirement for MRO recertification every five years, and recommended that MROs complete training every three years. Five commenters stated support for five year requalification and examination requirements. The Department has evaluated the comments and has concluded that no change is needed. The Department will keep the five-year requalification requirement as proposed. This is consistent with the MRO requalification requirement in the UrMG.

13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

One commenter agreed with MRO certification/training entities submitting the delivery method and content of the MRO examination as applicable along with other required documents. One commenter agreed with extending time from one to two years for approved MRO certification/training entities' resubmission of qualifications for HHS approval. The commenter noted that they would support further extension to 3 years.

One commenter recommended that approval of MRO educational courses and content be at the discretion of the MRO certification entities, not HHS. Since the certification entities and their examinations are subject to HHS oversight and approval, the commenter noted that it may be burdensome for HHS to review and approve the courses and content, and be a disincentive to development of new courses. One commenter recommended that examinations be allowed to be in-person or online with appropriate security precautions for each delivery method. The Department has evaluated the comments and agrees that the submission of training materials to HHS would possibly discourage the development of new training courses. Therefore, the review of MRO educational courses and content will not be part of the approval process for MRO certification entities. As described under *Medical Review Officer (MRO) requalification—continuing education units (CEUs)* in this preamble, the Department has removed references to MRO training entities in Section 13.2, because training documentation is maintained by MRO certification entities. The Department will only require the MRO certification entities to submit their examination and any other necessary supporting examination materials (*e.g.,* answers, examination statistics or background information on questions) that will help in the Department's evaluation of the examination. The Department has revised Section 13.2 accordingly.

The Department will review and evaluate the examination delivery method (*e.g.,* in-person or online) when reviewing submitted materials to ensure that the delivery method employs appropriate security and identification procedures.

13.3 What training is required before a physician may serve as an MRO?

Five commenters disagreed and one commenter agreed with the added requirement for MRO training to include information about how to discuss substance misuse and abuse and how to access those services. The Department has evaluated the comments and has revised Section 13.3 to remove this requirement. Federal agencies may provide this information to employees and applicants to facilitate their access to effective treatment and support recovery. The Department provides information to the public on help and treatment for substance misuse and abuse, and how to access those services, on the SAMHSA website *http://www.samhsa.gov/*.

One commenter stated that the Department should add a requirement for MRO training on what constitutes a refusal to test. One commenter suggested that the Department should add a requirement for MRO training on when and how to report safety concerns to employers when prescription and/or over-the-counter medications may affect performance. The Department has evaluated the comments and has concluded that no change is needed. Criteria for reporting a refusal to test are covered under the topics listed in Section 13.3 such as items (a)(4) training on the Guidelines and (a)(5) procedures for interpretation, review, and reporting of results. When a donor provides a legitimate medical explanation for a positive drug test (*e.g.,* a valid prescription), the Guidelines do not require MROs to contact federal agency employers for the purpose of reporting a safety concern. Accordingly, MRO training related to reporting ''safety concerns'' does not relate to a mandatory function under the Guidelines and, therefore, is not an essential component of required MRO training. The Department will provide additional guidance in the HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs.

In addition, the Department revised Section 13.3 as described under *Medical Review Officer (MRO) requalification—continuing education units (CEUs)* in this preamble. The Department removed references to MRO training entities because training documentation is maintained by MRO certification entities, and added item 13.3(b) to require MRO training on revised Guidelines prior to their effective date.

13.4 What are the responsibilities of an MRO?

One commenter suggested creating a subset of medical professionals trained specifically to determine fitness for duty since an MRO cannot determine fitness for duty over the telephone. The Department has evaluated the comment and has concluded that no change is needed. Fitness for duty evaluations fall outside the purview of the Guidelines.

13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

The Department has revised Section 13.5(c)(1) to include ''a valid prescription'' as an example of documentation to support a medical explanation for a positive drug test result.

As described under *Testing for Marijuana Use* in this preamble, the Department has revised Section 13.5(c)(1) to reflect the Department's policy that passive exposure to a drug (*e.g.,* exposure to secondhand marijuana smoke) and ingestion of food products containing marijuana are not legitimate medical explanations for a positive drug test result.

In Section 13.5(c)(2)(i), the Department clarified that the requirement for ''clinical evidence of illegal use'' does not apply if the laboratory confirms the presence of 6-

acetylmorphine (*i.e.,* the presence of this metabolite is proof of heroin use).

13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?

One commenter requested definition of ''appropriate expertise'' in medical issues raised by a donor's failure to provide a specimen. The same commenter requested medical referral information on the employer's actions when a donor could not provide a urine specimen and then could not provide an oral fluid specimen. The Department has evaluated the comments and has concluded that no change is needed. A physician who is a trained MRO will have the knowledge necessary to identify another physician with appropriate expertise for the medical evaluation. The Department will provide additional guidance in the HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs as appropriate when oral fluid is allowed in federal workplace drug testing programs.

The Department clarified the definition of ''permanent or long-term medical conditions'' in Section 13.6(b)(1) based on a federal agency comment.

Subpart O—Criteria for Rejecting a Specimen for Testing

15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?

The Department revised wording in items a and b of this section, and included three additional fatal flaws as items f-h, to reflect fatal flaws for regulated donor specimens that have been identified by HHS-certified laboratories. These fatal flaws were addressed in NLCP guidance sent to all HHS-certified and applicant laboratories and IITFs on August 9, 2016. In addition, the Department revised this section to include an additional item i to allow a laboratory to reject a specimen when they identify a flaw that prevents testing or affects the forensic defensibility of the drug test, and cannot be corrected. This general item enables laboratories to reject specimens with fatal flaws that may be rare, but do occur. It is not possible to list all such flaws in the Guidelines.

15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?

Two commenters indicated that inclusion of some items as insignificant discrepancies contradicts guidance provided to HHS-certified laboratories and IITFs in NLCP Notices, which required laboratories to attempt to recover missing information. One of these commenters suggested that if these items are important, they should be removed from the ''insignificant'' list. Two commenters disagreed with the Guidelines designating the listed omissions and discrepancies as ''insignificant only when they occur no more than once per month.'' The Department has evaluated the comments. The listed discrepancies would not result in rejection or cancellation. NLCP Notices requiring laboratory action are consistent with this section. However, the Department has reworded section 15.3 to not classify these errors as insignificant. While these types of errors do not warrant laboratory rejection of a specimen or MRO cancellation of a test, as noted in section 15.3(c), corrective action must be initiated when they occur more than once a month.

The commenters indicated that this section implies that the MRO must keep a log of insignificant errors by laboratory and by collection site in order to track frequency. The commenters noted that this is an unenforceable policy, that this should be a duty of inspectors of laboratories and collection sites, and that requiring MROs to keep these types of logs would create significant extra costs. One commenter suggested that item 15.3(c) be modified for the MRO to advise the collector or laboratory to retrain staff on relevant procedures to ensure that collections are completed correctly (rather than directing them to immediately take corrective action). The Department has evaluated the comments and has concluded that no change is needed. This section is the same as in the Guidelines effective October 1, 2010 (73 FR 71858).

One commenter suggested modifying 15.3(a)(5) to read ''donor identification number'' which would include a social security number or an employee identification number since many employers no longer use social security numbers for employee identification. The Department agrees and has revised Section 15.3(a)(5) to include ''employee identification number'' in addition to ''Social Security Number.''

15.4 What discrepancies may require an MRO to cancel a test?

One commenter suggested adding the scenario where the donor did not sign the CCF because the collector forgot to ask the donor to sign, rather than the donor's refusal to sign. The Department has evaluated the comment and has concluded that no change is needed. As stated in Section 15.4, the MRO contacts the collector ''to obtain a statement to verify that the donor refused to sign the MRO copy.''

Regulatory Impact and Notices

Executive Order 12866

The Secretary has examined the impact of the Guidelines under Executive Order 12866, which directs federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). In addition, the Department published a **Federal Register** notice in June 2011 to solicit comments regarding the science and practice of oral fluid testing via a Request for Information (RFI) [76 FR 34086].

According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. The Guidelines do establish additional regulatory requirements and allow an activity that was otherwise prohibited. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for ''a matter relating to agency management or personnel'' 5 U.S.C. 553(a)(2). Because the Guidelines issued by the Secretary govern federal workplace drug testing programs, HHS has taken the position that the Guidelines are a ''matter relating to agency management or personnel'' and, thus, are not subject to the APA's requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs.

The Department included a Regulatory Impact and Notices section with cost and benefits analysis and burden estimates in the May 15, 2015

Federal Register Notice for the proposed OFMG (80 FR 28054), and requested public comment on all estimates and assumptions.

One commenter disagreed with the Department's projected numbers of oral fluid and urine drug tests by federal agencies and industries regulated by the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC). This commenter predicted that there will be a large shift from urine to oral fluid testing when oral fluid is allowed in regulated testing, stating that the oral fluid collection is a more efficient and direct process for the collector, oral fluid is much less likely to be adulterated than urine, oral collections are quicker than most urine collections, and oral fluid is looked upon favorably from a hygienic perspective by donors and collectors. The commenter did not provide any substantive evidence or data to support these comments. One commenter disagreed with inclusion of cost estimates within the Guidelines due to the difficulty in comparing urine and oral fluid costs. The Department has evaluated the comments and has concluded that no change is needed. The Department's projections were developed using information from current HHS-certified urine testing laboratories, with input from DOT and NRC, and cost analysis was based on information provided by multiple oral fluid testing laboratories and MROs. Each federal agency will decide whether to collect urine, oral fluid, or both specimen types in their workplace testing programs, and DOT and NRC will decide whether to allow oral fluid testing in workplace drug testing regulations for their regulated industries. Costs are expected to vary among individual laboratories and MROs, depending on their processes and testing populations. Additional information on the estimated costs associated is below.

Need for Regulation

Enhances Flexibility

The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) revise the requirement to collect only a urine specimen, which has existed since the Guidelines were first published in 1988, while continuing to promulgate established standards to ensure the full reliability and accuracy of drug test results. Urine testing is subject to issues related to a donor's inability to produce a urine specimen due to a legitimate medical condition. In such situations, the test may produce an invalid result or create delays accruing from the need to reschedule the test or medically assess the donor's inability to provide a urine sample. When the OFMG are implemented by an agency, such agency will be authorized to collect an oral fluid specimen from an individual who is unable to provide a urine specimen. This added flexibility will reduce both the need to reschedule collections and the need for the Medical Review Officer (MRO) to arrange a medical evaluation of a donor's inability to provide a specimen. Therefore, the OFMG provide flexibility to address workplace drug testing needs of federal agencies by permitting the selection of the specimen type best suited for their needs and authorizing collection of an alternative specimen type when a donor is unable to provide a specimen. The added flexibility will also benefit donors, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

Enhances Versatility

Urine collection requires use of a specialized collection facility, secured restrooms, the same gender, and other special requirements. Oral fluid may be collected in various settings. An acceptable oral fluid collection site must allow the collector to observe the donor, maintain control of the collection device(s) during the process, maintain record storage, and protect donor privacy.

Decreases Invalid Tests

All unobserved specimen collections are at risk for substitution and adulteration. Studies conducted by the drug testing industry indicate that 0.05 to 3% of urine specimens collected for drug use detection are determined to be substituted or adulterated.[5 27 28] Oral fluid collections will occur under observation, which should substantially lessen the risks of specimen substitution and adulteration that has been associated with urine specimen collections, most of which are unobserved. Specimen validity testing of oral fluid specimens will be allowed to identify invalid specimens (*e.g.,* testing for a biomarker such as albumin or immunoglobulin G, IgG).

Saves Time

Oral fluid collection can require less time than urine collection, reducing employee time away from the workplace and, therefore, reducing costs to the federal agency employer. Oral fluid collection does not require a facility that provides visual privacy during the collection. Unlike urine specimen collections, it is expected that many oral fluid collections will occur at or near the workplace, and not at a dedicated collection site, thereby reducing the amount of time away from the workplace. The collector is allowed to be in the vicinity of the donor, reducing the loss of productive time. The option to collect a urine specimen in the event that the donor cannot provide an oral fluid specimen (and vice versa) will reduce both the need to reschedule a collection and the need for the MRO to arrange a medical evaluation of a donor's inability to provide a specimen. Administrative data for urine collections indicates it takes, on average, about 4 hours from the start of the notification of the drug test to the actual time a donor reports back to the worksite. Since oral fluid collection does not have the same privacy concerns as urine collection, onsite collections are likely, thereby reducing the time a donor is away from the worksite. The Department estimates the time savings to be more than 2 hours. This estimate takes into account the time savings if the oral fluid collection was conducted at the employee's workplace, and thus incorporates travel time savings. Using OPM's estimate for the average annual salary of Federal employees converted to an hourly wage, the savings generated for the Federal Government would be roughly $400,000 to $1.2 million a year, or $38 to $114 per test.

Versatility in Detection

The time course of drugs and metabolites differs between oral fluid and urine, resulting in some differences in analytes and detection times. Oral fluid tests generally are positive as soon as the drug is absorbed into the body. In contrast, urine tests that are based solely on detection of a metabolite are dependent upon the rate and extent of metabolite formation. Thus, oral fluid may permit more interpretative insight into recent drug use drug-induced effects that may be present shortly before or at the time the specimen is collected. A federal agency may select the specimen type for collection based on the circumstances of the test. For example, in situations where drug use at the work-site is suspected, the testing of oral fluid may show the presence of an active drug, which may indicate recent administration of the drug and be advantageous when assessing whether the drug contributed to an observed behavior.

Current Testing in the Drug Free Workplace Program

Urine was the original specimen of choice for forensic workplace drug

testing, and urine testing is expected to remain an established and reliable component of federal workplace drug testing programs. Urine testing provides scientifically accurate and legally defensible results and has proven to be an effective deterrent to drug use in the workplace.

A major challenge to urine drug testing has been the proliferation of commercial products used to adulterate or substitute a donor's urine specimen. Due to individual privacy rights, most urine collections are unobserved, allowing the opportunity to use such products. As the Department has established requirements and laboratories have developed procedures to control for adulterated and substituted specimens, manufacturers have developed new products to avoid detection. The use of these products is expected to continue.

Cost and Benefit

Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, the Department estimates the number of specimens tested annually for federal agencies to be 150,000. The Department projects that approximately 7% (or 10,500) of the 150,000 specimens tested per year will be oral fluid specimens and 93% (or 139,500) will be urine specimens. The subsequent transition to oral fluid testing is expected to be gradual and steady over the course of four years, when it should plateau to account for 25 to 30% of federal agency drug testing (*i.e.,* 37,500 to 45,000 specimens). This transition estimate is based on the non-regulated sector's time course of the testing of oral fluid and urine in the four years preceding the final OFMG.

The approximate annual numbers of regulated specimens collected from applicants and employees under the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) drug testing regulations are 6 million and 155,000, respectively. Should DOT and NRC allow oral fluid testing in regulated industries' workplace programs, the estimated annual numbers of specimens for DOT would be 180,000 oral fluid and 5,820,000 urine, and numbers of specimens for NRC would be 10,850 oral fluid and 144,150 urine. Assuming the same four-year transition time for DOT- and NRC-regulated industries, the numbers of oral fluid specimens are expected to be 1,500,000 to 1,800,000 specimens under DOT regulations and 38,750 to 46,500 specimens under NRC regulations.

In Section 3.4, the Department included criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specified the cross-reactivity of the immunoassay to the other analytes(s) within the group. These Guidelines allow the use of methods other than immunoassay for initial testing. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

Costs associated with the addition of oral fluid testing and testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal based on information from some HHS-certified laboratories currently testing private sector oral fluid specimens.

Prior to being allowed to test regulated oral fluid specimens, laboratories must be certified by the Department through the NLCP. Estimated laboratory costs to complete and submit the application are $3,000, and estimated costs for the Department to process the application are $7,200. These estimates are from SAMHSA and are based on the NLCP fee schedule and historical costs. The initial certification process includes the requirement to demonstrate that the applicant laboratory's performance meets Guidelines requirements by testing three (3) groups of PT samples. The Department will provide the three groups of PT samples through the NLCP at no cost. Based on costs charged for urine specimen testing, laboratory costs to conduct the PT testing would range from $900 to $1,800 for each applicant laboratory.

Agencies choosing to use oral fluid in their drug testing programs may also incur some costs for training of federal employees such as drug program coordinators. Based on current training modules offered to drug program coordinators, and other associated costs including travel for 90% of drug program coordinators, the estimated total training cost for a one-day training session would be between $108,000 and $138,000 (*i.e.,* assuming 8 hours of time multiplied by a GS 12/13 wage including benefits and overhead adjustments). This training cost is included in the costs of the revised URMG. The Department will offer the choice of online or in-person training. This will eliminate travel costs for those federal agencies who choose to use online training.

SUMMARY OF ONE-TIME COSTS

	Lower bound	Upper bound	Primary
Cost of Application *			$93,000.00
Application Processing *			217,000.00
Performance Testing *	$27,900.00	$55,800.00	
Training *	108,000.00	138,000.00	
Total	445,900.00	503,800.00	

* Estimated using costs presented above multiplied by the number of Laboratories (31).

Costs and Benefits

Thus, the Department estimates one-time, upfront costs of between $446,000 and $504,000. While the Department has only monetized a small portion of the benefits (time savings) to a small subset of the workplace drug testing programs that could be affected by the OFMG (*i.e.,* federal employee testing programs and not drug testing programs conducted under NRC and DOT regulations), the Department is confident that the benefits would outweigh the costs. Even if NRC and DOT do not implement oral fluid testing for their regulated industries' drug testing programs, the benefits to Federal workplace testing programs, estimated at between $400,000 and $1.2 million, would recur on an annual basis.

Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This set of Guidelines is considered an E.O. 13771 deregulatory action. The net cost savings, annualized over a perpetual time horizon using a 7% discount rate and expressed in 2016 dollars, is estimated to be $87.34 million.

Regulatory Flexibility Analysis

For the reasons outlined above, the Secretary has determined that the Guidelines will not have a significant impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act [5 U.S.C. 605(b)]. The flexibility added by the OFMG will not require additional expenditures. Therefore, a final regulatory flexibility analysis is not required for this notice.

As mentioned in the section on Executive Order 12866, the Secretary anticipates that there will be an overall reduction in costs if drug testing is expanded under the OFMG. The costs to implement this change to regulation are negligible. The added flexibility will permit federal agencies to select the specimen type best suited for their needs and to authorize collection of an alternative specimen type when an employee is unable to provide the originally authorized specimen type. Insofar as there are costs associated with each drug test, this could lead to lower overall testing costs for federal agencies. The added flexibility will also benefit federal employees, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

The Secretary has determined that the Guidelines are not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. This is not a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

Unfunded Mandates

The Secretary has examined the impact of the Guidelines under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice does not trigger the requirement for a written statement under section 202(a) of the UMRA because the Guidelines do not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by either state, local, and tribal governments in the aggregate or by the private sector in any one year.

Environmental Impact

The Secretary has considered the environmental effects of the OFMG. No information or comments have been received that would affect the agency's determination there would be a significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

Executive Order 13132: Federalism

The Secretary has analyzed the Guidelines in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt state law. As defined in the Order, ''policies that have federalism implications'' refer to regulations, legislative comments or proposed legislation, and other policy statements or actions 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.

In this notice, the Secretary establishes standards for certification of laboratories engaged in oral fluid drug testing for federal agencies and the use of oral fluid testing in federal drug-free workplace programs. The Department of Health and Human Services, by authority of Section 503 of Public Law 100–71, 5 U.S.C. 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for federal agencies. Because the Mandatory Guidelines govern standards applicable to the management of federal agency personnel, there should be little, if any, 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. Accordingly, the Secretary has determined that the Guidelines do not contain policies that have federalism implications.

Privacy Act

The Secretary has determined that the Guidelines do not contain information collection requirements constituting a system of records under the Privacy Act. The **Federal Register** notice announcing the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid is not a system of records as noted in the information collection/recordkeeping requirements below. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** on April 11, 1988 [53 FR 11979]. SAMHSA subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008 [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809]. The revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) were published on January 23, 2017 [82 FR 7920] with an effective date of October 1, 2017.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires SAMHSA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' as defined in the Executive Order, include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the federal government and the Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.'' The Guidelines do not have tribal implications. The Guidelines will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175.

Information Collection/Record Keeping Requirements

The information collection requirements (*i.e.,* reporting and recordkeeping) in the current Guidelines (82 FR 7920), which establish the scientific and technical guidelines for federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine drug testing for federal agencies under authority of 5 U.S.C. 7301 and Executive Order 12564, are approved by the Office of Management and Budget (OMB) under control number 0930–0158. The Federal Drug Testing Custody and Control Form used to document the collection and chain of custody of urine

specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination, the National Laboratory Certification Program (NLCP) application, the NLCP Laboratory Information Checklist, and recordkeeping requirements in the current Guidelines, as approved under control number 0930–0158, will remain in effect for regulated urine drug testing under the UrMG. The same documents specifically for regulated oral fluid drug testing under the OFMG will be submitted for OMB approval under a new control number.

The title, description, and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting, disclosure and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid Specimens

Description: The Guidelines establish the scientific and technical guidelines for federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 note, and Executive Order No. 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions. The program has depended on urine specimen testing since 1988; the reporting, recordkeeping and disclosure requirements associated with urine specimen testing are approved under OMB control number 0930–0158. These Guidelines establish when oral fluid specimens may be collected, the procedures that must be used in collecting an oral fluid specimen, and the certification process for approving a laboratory to test oral fluid specimen.

Description of Respondents: Individuals or households; businesses; or other-for-profit; not-for-profit institutions.

The annual burden estimates in the tables below are based on the following number of respondents: 10,500 donors who apply for employment or are employed in testing designated positions, 100 collectors, 10 oral fluid specimen testing laboratories, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
9.2(a)(1)	Laboratory required to submit application for certification.	10	1	3	30
9.10(a)(3)	Materials to submit to become an HHS inspector.	10	1	2	20
11.3(a)	Laboratory submits qualifications of RP to HHS	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP.	10	1	2	20
11.20	Specifications for laboratory semi-annual statistical report of test results to each federal agency.	10	5	0.5	25
13.9 & 14.6	Specifies that MRO must report all verified primary and split specimen test results to the federal agency.	100	14	* 0.05	70
16.1(b) & 16.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification.	1	1	3	3
16.4	Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed.	1	1	0.5	0.5
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period.	1	1	0.5	0.5
16.7(a)	Specifies contents of appellant submission for review.	1	1	50	50
16.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation.	1	1	3	3
16.9(c)	Specifies contents of review file and briefs	1	1	50	50
Total		156			292

* (3 min).

The following reporting requirements are also in the Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or refuse to participate in the collection process on the Federal CCF (sections 1.8, 8.9); collector annotates the Federal CCF when a sample is a blind sample (section 10.3(a)); MRO notifies the federal agency and HHS when an error occurs on a blind sample (section 10.4(c)); section 13.5 describes the actions an MRO takes to report a primary specimen result; and section 14.5 describes the actions an MRO takes to report a split specimen result. SAMHSA has not calculated a separate reporting burden for these requirements because they will be included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to federal agencies.

ESTIMATE OF ANNUAL DISCLOSURE BURDEN

Section	Purpose	No. of respondents	Responses/ respondent	Hours/ response	Total hours
8.3(a) & 8.6(b)(2)	Collector must contact federal agency point of contact.	100	1	*0.05	5
11.21 & 11.22	Information on drug test that laboratory must provide to federal agency upon request or to donor through MRO.	50	10	3	1,500
13.8 (b)	MRO must inform donor of right to request split specimen test when a positive or adulterated result is reported.	100	14	3	4,200
Total		210			5,705

*(3 min).

The following disclosure requirements are also included in the Guidelines, but have not been addressed in the above disclosure burden table: The collector must explain the basic collection procedure to the donor and answer any questions (section 8.3(f) and (h), and must review the procedures for the oral fluid specimen collection device used with the donor (section 8.4(b)). The Department believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	No. of respondents	Responses/ respondent	Hours/ response	Total hours
8.3, 8.5, & 8.8	Collector completes Federal CCF for specimen collected.	100	380	0.07 (4 min)	2,534
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF.	10,500	1	0.08 (5 min)	875
11.8(a) & 11.17	Laboratory completes Federal CCF upon receipt of specimen and before reporting result.	10	3,800	0.05 (3 min)	1,900
13.4(d) (4), 13.9 (c), & 14.6(c).	MRO completes Federal CCF before reporting the result.	100	380	0.05 (3 min)	1,900
14.1(b)	MRO documents donor's request to have split specimen tested.	300	1	0.05 (3 min)	15
Total		11,010			7,224

The Guidelines contain a number of recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector [section 4.3(a)(3)] and the documentation must be maintained in the collector's training file [section 4.3(c)]. Because this is required by the current Guidelines using urine specimens as well as these Guidelines using oral fluid specimens and is consistent with general forensic requirements, SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a federal agency specimen, the collector is required to provide a statement [section 6.2(b)] explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H [sections 8.4(d) and 8.5(a)(1)] requires collectors to enter any information on the Federal CCF of any unusual findings during the oral fluid specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subparts K describe a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records (*i.e.,* sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.10(1); 11.13(a); 11.16; 11.17(a), (b), and (c); 11.20; 11.21, and 11.22. These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis.

Thus, the total annual response burden associated with the testing of oral fluid specimens by the laboratories is estimated to be 13,221 hours (that is, the sum of the total hours from the above tables). Because of the expected transition from urine to oral fluid testing, this number will replace some of the 1,788,809 hours currently approved by OMB under control number 0930–0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary submitted a copy of the proposed Guidelines to OMB for its review. Comments on the information collection requirements were specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS's estimate of the burden of the proposed

collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

References

1. Cone, E.J., 1990. Testing human hair for drugs of abuse. I. Individual dose and time profiles of morphine and codeine in plasma, saliva, urine, and beard compared to drug-induced effects on pupils and behavior. *J Anal Toxicol,* 14, 1–7.
2. Cone, E.J., Clarke, J., Tsanaclis, L., 2007. Prevalence and disposition of drugs of abuse and opioid treatment drugs in oral fluid. *J Anal Toxicol,* 31, 424–433.
3. Petrides, A.K., Melanson, SEF., Kantartjis, M., Le, R.D., Demetriou, C.A., Flood, J.G., 2018. Monitoring opioid and benzodiazepine use and abuse: Is oral fluid or urine the preferred specimen type? *Clin Chim Acta,* 481, 75–82.
4. Vindenes, V., Yttredal, B., Øiestad, E.L., Waal, H., Bernard, J.P., Mørland, J.G., Christophersen, A.S., 2011. Oral fluid is a viable alternative for monitoring drug abuse: Detection of drugs in oral fluid by liquid chromatography-tandem mass spectrometry and comparison to the results from urine samples from patients treated with Methadone or Buprenorphine. *J Anal Toxicol,* 35, 32–39.
5. Quest Diagnostics, 2018. Workforce drug positivity at highest rate in a decade, finds analysis of more than 10 million drug test results. *https://www.questdiagnostics.com/dms/Documents/Employer-Solutions/DTI–2018/2018-quest-diagnostics-drug-testing-index-2018-report/2018QuestDiagnosticsDrugTestingIndex.pdf* Accessed October 19, 2018.
6. Dams, R., Choo, R.E., Lambert, W.E., Jones, H., Huestis, M.A., 2007. Oral fluid as an alternative matrix to monitor opiate and cocaine use in substance-abuse treatment patients. *Drug Alcohol Depend,* 87, 258–267.
7. Cone, E.J., 2012. Oral fluid results compared to self reports of recent cocaine and heroin use by methadone maintenance patients. *Forensic Sci Int,* 215, 88–91.
8. Niedbala, R.S., Kardos, K.W., Fritch, D.F., Kardos, S., Fries, T., Waga, J., Robb, J., Cone, E.J., 2001. Detection of marijuana use by oral fluid and urine analysis following single-dose administration of smoked and oral marijuana. *J Anal Toxicol,* 25, 289–303.
9. Niedbala, R.S., Kardos, K.W., Fritch, D.F., Kunsman, K.P., Blum, K.A., Newland, G.A., Waga, J., Kurtz, L., Bronsgeest, M., Cone, E.J., 2005. Passive cannabis smoke exposure and oral fluid testing. II. Two studies of extreme cannabis smoke exposure in a motor vehicle. *J Anal Toxicol,* 29, 607–615.
10. Moore, C., Coulter, C., Uges, D., Tuyay, J., van der Linde, S., van Leeuwen, A., Garnier, M., Orbita, J. Jr., 2011. Cannabinoids in oral fluid following passive exposure to marijuana smoke. *Forensic Sci Int,* 212, 227–230.
11. Niedbala, S., Kardos, K., Salamone, S., Fritch, D., Bronsgeest, M., Cone, E.J., 2004. Passive cannabis smoke exposure and oral fluid testing. *J Anal Toxicol,* 28, 546–552.
12. Herrmann, E.S., Cone, E.J., Mitchell, J.M., Bigelow, G.E., LoDico, C., Flegel, R., Vandrey, R., 2015. Non-smoker exposure to secondhand cannabis smoke. II. Effect of room ventilation on the physiological, subjective, and behavioral/cognitive effects. *Drug Alcohol Depend,* 151, 194–202.
13. Cone, E.J., Bigelow, G.E., Herrmann, E.S., Mitchell, J.M., LoDico, C., Flegel, R., Vandrey, R., 2015. Nonsmoker exposure to secondhand cannabis smoke. III. Oral fluid and blood drug concentrations and corresponding subjective effects. *J Anal Toxicol,* 39, 497–509.
14. SUPPORT for Patients and Communities Act, H.R. 6, 115th Cong. (2018). *https://www.congress.gov/bill/115th-congress/house-bill/6.*
15. Swortwood, M.J., Newmeyer, M.N., Andersson, M., Abulseoud, O.A., Scheidweiler, K.B., Huestis, M.A., 2017. Cannabinoid disposition in oral fluid after controlled smoked, vaporized, and oral cannabis administration. *Drug Test Anal,* 9, 905–915.
16. Vandrey, R., Herrmann, E.S., Mitchell, J.M., Bigelow, G.E., Flegel, R., LoDico, C., Cone, E.J., 2017. Pharmacokinetic profile of oral cannabis in humans: blood and oral fluid disposition and relation to pharmacodynamic outcomes. *J Anal Toxicol,* 41, 83–89.
17. Anizan, S., Milman, G., Desrosiers, N., Barnes, A.J., Gorelick, D.A., Huestis, M.A., 2013. Oral fluid cannabinoid concentrations following controlled smoked cannabis in chronic frequent and occasional smokers. *Anal Bioanal Chem,* 405, 8451–8461.
18. Desrosiers, N.A., Ramaekers, J.G., Chauchard, E., Gorelick, D.A., Huestis, M.A., 2015. Smoked cannabis' psychomotor and neurocognitive effects in occasional and frequent smokers. *J Anal Toxicol,* 39, 251–261.
19. Lee, D., Milman, G., Barnes, A.J., Goodwin, R.S., Hirvonen, J., Huestis, M.A., 2011. Oral fluid cannabinoids in chronic, daily cannabis smokers during sustained, monitored abstinence. *Clin Chem,* 57, 1127–1136.
20. Lee, D., Schwope, D.M., Milman, G., Barnes, A.J., Gorelick, D.A., Huestis, M.A., 2012. Cannabinoid disposition in oral fluid after controlled smoked cannabis. *Clin Chem,* 58, 748–756.
21. Rohrig, T.P., Moore, C., 2003. The determination of morphine in urine and oral fluid following ingestion of poppy seeds. *J Anal Toxicol,* 27, 449–452.
22. Samano, K.L., Clouette, R.E., Rowland, B.J., Sample, R.H.B., 2015. Concentrations of morphine and codeine in paired oral fluid and urine specimens following ingestion of a poppy seed roll and raw poppy seeds. *J Anal Toxicol,* 39, 655–661.
23. Newmeyer, M.N., Concheiro, M., da Costa, J.L., LoDico, C., Gorelick, D.A., Huestis, M.A., 2015. Simultaneous plasma and oral fluid morphine and codeine concentrations after controlled administration of poppy seeds with known opiate content. *Forensic Toxicol,* 33, 235–243.
24. Concheiro, M., Newmeyer, M.N., da Costa, J.L., Flegel, R., Gorelick, D.A., Huestis, M.A., 2015. Morphine and codeine in oral fluid after controlled poppy seed administration. *Drug Test Anal,* 7, 586–591.
25. Cone, E.J., DePriest, A.Z., Heltsley, R., Black, D.L., Mitchell, J.M., LoDico, C., Flegel, R., 2015. Prescription opioids. III. Disposition of oxycodone in oral fluid and blood following controlled single dose administration. *J Anal Toxicol,* 39, 192–202.
26. Cone, E.J., DePriest, A.Z., Heltsley, R., Black, D.L., Mitchell, J.M., LoDico, C., Flegel, R., 2015. Prescription opioids. IV. Disposition of hydrocodone in oral fluid and blood following single dose administration. *J Anal Toxicol,* 39: 510–518.
27. Goggin, M.M., Tann, C., Miller, A., Nguyen, A., Janis, G.C., 2017. Catching fakes: New markers of urine sample validity and invalidity. *J Anal Toxicol,* 41, 121–126.
28. Kluge, J., Rentzsch, L., Remane, D., Peters, F.T., Wissenbach, D.K., 2018. Systematic investigations of novel validity parameters in urine drug testing and prevalence of urine adulteration in a two-year cohort. *Drug Test Anal,* 10,1536–1542.

Dated: October 7, 2019.

Elinore F. McCance-Katz,

Assistant Secretary for Mental Health and Substance Use.

Dated: October 7, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

The Mandatory Guidelines using Oral Fluid Specimens are hereby adopted in accordance with section 503 of Public Law 100–71 and Executive Order 12564.

Mandatory Guidelines For Federal Workplace Drug Testing Programs Using Oral Fluid Specimens

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Subpart A—Applicability

Section 1.1 To whom do these Guidelines apply?

(a) These Guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));

(3) Any other employing unit or authority of the federal government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and

(4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories that provide drug testing services to the federal agencies;

(6) Collectors who provide specimen collection services to the federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the federal agencies.

(b) These Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.[1]

Section 1.2 Who is responsible for developing and implementing these Guidelines?

(a) Executive Order 12564 and Public Law 100–71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for federal workplace drug testing programs.

(b) The Secretary has the responsibility to implement these Guidelines.

Section 1.3 How does a federal agency request a change from these Guidelines?

(a) Each federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

Section 1.4 How are these Guidelines revised?

(a) To ensure the full reliability and accuracy of specimen tests, the accurate reporting of test results, and the integrity and efficacy of federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

(b) The changes will be published in final as a notice in the **Federal Register**.

Section 1.5 What do the terms used in these Guidelines mean?

The following definitions are adopted:

Accessioner. The individual who signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

[1] The NRC-related information in this notice pertains to individuals subject to drug testing conducted pursuant to 10 CFR Part 26, ''Fitness for Duty Programs'' (*i.e.,* employees of certain NRC-regulated entities).

Although HHS has no authority to regulate the transportation industry, the Department of Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regulated industry that ''incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988 and any amendments to those guidelines . . .'' See, *e.g.,* 49 U.S.C. §20140(c)(2). In carrying out its mandate, DOT requires by regulation at 49 CFR Part 40 that its federally-regulated employers use only HHS-certified laboratories in the testing of employees, 49 CFR §40.81, and incorporates the scientific and technical aspects of the HHS Mandatory Guidelines.

Adulterated Specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

Aliquot. A portion of a specimen used for testing.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

Alternate Technology Initial Drug Test. An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

Batch. A number of specimens or aliquots handled concurrently as a group.

Biomarker. An endogenous substance used to validate a biological specimen.

Blind Sample. A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

Calibrator. A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

Cancelled Test. The result reported by the MRO to the federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

Carryover. The effect that occurs when a sample result (*e.g.,* drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

Chain of Custody (COC) Procedures. Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Documents. Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

Collection Device. A product that is used to collect an oral fluid specimen and may include a buffer or diluent.

Collection Site. The location where specimens are collected.

Collector. A person trained to instruct and assist a donor in providing a specimen.

Confirmatory Drug Test. A second analytical procedure performed on a separate aliquot of a specimen to identify and quantify a specific drug or drug metabolite.

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a specimen to further support a specimen validity test result.

Control. A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Cutoff. The analytical value (*e.g.,* drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or, for urine, substituted) or the need for further testing.

Donor. The individual from whom a specimen is collected.

External Service Provider. An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or, for urine, an HHS-certified Instrumented Initial Test Facility (IITF).

Failed to Reconfirm. The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

Federal Drug Testing Custody and Control Form (Federal CCF). The Office of Management and Budget (OMB) approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

HHS. The Department of Health and Human Services.

Initial Drug Test. An analysis used to differentiate negative specimens from those requiring further testing.

Initial Specimen Validity Test. The first analysis used to determine if a specimen is invalid, adulterated, or (for urine) diluted or substituted.

Instrumented Initial Test Facility (IITF). A permanent location where (for urine) initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

Invalid Result. The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.7 when a positive or negative result cannot be established for a specific drug or specimen validity test.

Laboratory. A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Limit of Detection. The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantification. For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

Lot. A number of units of an item (*e.g.,* reagents, quality control material, oral fluid collection device) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

Medical Review Officer (MRO). A licensed physician who reviews, verifies, and reports a specimen test result to the federal agency.

Negative Result. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

Oral Fluid Specimen. An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

Oxidizing Adulterant. A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of

the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

Performance Testing (PT) Sample. A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

Positive Result. The result reported by an HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the confirmation cutoff concentration.

Reconfirmed. The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2)

Responsible Person (RP). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of an HHS-certified laboratory.

Sample. A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

Secretary. The Secretary of the U.S. Department of Health and Human Services.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Oral Fluid). A collection in which two specimens [primary (A) and split (B)] are collected, concurrently or serially, and independently sealed in the presence of the donor; or a collection in which a single specimen is collected using a single collection device and is subdivided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

Standard. Reference material of known purity or a solution containing a reference material at a known concentration.

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example, see Section 2.4: A collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Section 1.6 What is an agency required to do to protect employee records?

Consistent with 5 U.S.C. 552a and 48 CFR 24.101–24.104, all agency contracts with laboratories, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100–71. Each federal agency must establish a Privacy Act System of Records or modify an existing system or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, Subparts A and E, may be applicable to certain health care providers with whom a federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit *http://www.hhs.gov/ocr/hipaa.*

Section 1.7 What is a refusal to take a federally regulated drug test?

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the federal agency, consistent with applicable agency regulations, after being directed to do so by the federal agency;

(2) Fail to remain at the collection site until the collection process is complete with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test as described in section 8.4(a);

(3) Fail to provide a specimen (*e.g.,* oral fluid or another authorized specimen type) for any drug test required by these Guidelines or federal agency regulations with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test as described in section 8.4(a);

(4) Fail to provide a sufficient amount of oral fluid when directed, and it has been determined, through a required medical evaluation, that there was no legitimate medical explanation for the failure as determined by the process described in Section 13.6;

(5) Fail or decline to participate in an alternate specimen collection (*e.g.,* urine) as directed by the federal agency or collector (*i.e.,* as described in Section 8.6);

(6) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (*i.e.,* Section 13.6) or as directed by the federal agency. In the case of a federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(7) Fail to cooperate with any part of the testing process (*e.g.,* disrupt the collection process; fail to rinse the mouth after being directed to do so by the collector; refuse to provide a split specimen);

(8) Bring materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen;

(9) Attempt to adulterate, substitute, or dilute the specimen; or

(10) Admit to the collector or MRO that you have adulterated or substituted the specimen.

Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

(a) As a federal agency employee or applicant, a refusal to take a test may result in the initiation of disciplinary or adverse action, up to and including removal from, or non-selection for, federal employment.

(b) When a donor has refused to participate in a part of the collection process, including failing to appear in a reasonable time for any test except a pre-employment test as described in Section 1.7(a)(1), the collector must terminate the collection process and take action as described in Section 8.9. Required action includes immediately notifying the federal agency's designated representative by any means (*e.g.,* telephone or secure fax machine) that ensures that the refusal notification is immediately received and, if a Federal CCF has been initiated, documenting the refusal on the Federal CCF, signing and dating the Federal

CCF, and sending all copies of the Federal CCF to the federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

(1) Checking the refusal to test box;

(2) Providing a reason for the refusal in the remarks line; and

(3) Signing and dating the MRO copy of the Federal CCF.

Subpart B—Oral Fluid Specimens

Section 2.1 What type of specimen may be collected?

A federal agency may collect oral fluid and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using oral fluid must follow these Guidelines.

Section 2.2 Under what circumstances may an oral fluid specimen be collected?

A federal agency may collect an oral fluid specimen for the following reasons:

(a) Federal agency applicant/Pre-employment test;

(b) Random test;

(c) Reasonable suspicion/cause test;

(d) Post accident test;

(e) Return to duty test; or

(f) Follow-up test.

Section 2.3 How is each oral fluid specimen collected?

Each oral fluid specimen is collected as a split specimen (*i.e.,* collected either simultaneously or serially) as described in Sections 2.5 and 8.8.

Section 2.4 What volume of oral fluid is collected?

A volume of at least 1 mL of undiluted (neat) oral fluid for each oral fluid specimen (designated ''Tube A'' and ''Tube B'') is collected using a collection device. If the device does not include a diluent (or other component, process, or method that modifies the volume of the testable specimen), the A and B tubes must have a volume marking clearly noting a level of 1 mL.

Section 2.5 How is the split oral fluid specimen collected?

The collector collects at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''A'' (primary) and at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''B'' (split) either simultaneously or serially (*i.e.,* using two devices or using one device and subdividing the specimen), as described in Section 8.8.

Section 2.6 When may an entity or individual release an oral fluid specimen?

Entities and individuals subject to these Guidelines under Section 1.1, may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71 and these Guidelines, to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.8.

Subpart C—Oral Fluid Drug and Specimen Validity Tests

Section 3.1 Which tests are conducted on an oral fluid specimen?

A federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine as provided under Section 3.4;

(b) Is authorized to test each specimen for opioids, amphetamines, and phencyclidine, as provided under Section 3.4; and

(c) Is authorized upon a Medical Review Officer's request to test an oral fluid specimen to determine specimen validity using, for example, a test for a biomarker such as albumin or immunoglobulin G (IgG) or a test for a specific adulterant.

(d) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

Section 3.2 May a specimen be tested for additional drugs?

(a) On a case-by-case basis, a specimen may be tested for additional drugs, if a federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a federal agency employee may be tested by the federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act. The federal agency must request the HHS-certified laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the federal agency can request an HHS-certified laboratory to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(b) A federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in Section 3.1. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

Section 3.3 May any of the specimens be used for other purposes?

(a) Specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. Use of specimens by donors, their designees or any other entity, for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable federal law.

(b) These Guidelines are not intended to prohibit federal agencies specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

Section 3.4 What are the drug test cutoff concentrations for undiluted (neat) oral fluid?

Initial test analyte	Initial test cutoff [1] (ng/mL)	Confirmatory test analyte	Confirmatory test cutoff concentration (ng/mL)
Marijuana (THC) [2]	[3] 4	THC	2
Cocaine/Benzoylecgonine	15	Cocaine	8
		Benzoylecgonine	8
Codeine/Morphine	30	Codeine	15
		Morphine	15
Hydrocodone/Hydromorphone	30	Hydrocodone	15
		Hydromorphone	15
Oxycodone/Oxymorphone	30	Oxycodone	15
		Oxymorphone	15
6-Acetylmorphine	[3] 4	6-Acetylmorphine	2
Phencyclidine	10	Phencyclidine	10
Amphetamine/Methamphetamine	50	Amphetamine	25
		Methamphetamine	25
MDMA [4]/MDA [5]	50	MDMA	25
		MDA	25

[1] *For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):*
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.*, equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol (THC).
[3] *Alternate technology (THC and 6–AM):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.*, 2 ng/mL for THC, 2 ng/mL for 6–AM).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests on a case-by-case basis as necessary to provide information that the MRO would use to report a verified drug test result (*e.g.,* specimen validity tests including biomarker and/or adulterant tests, tetrahydrocannabivarin). An HHS-certified laboratory is not authorized to routinely perform additional drug and/or specimen validity tests at the request of an MRO without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. All tests must meet appropriate validation and quality control requirements in accordance with these Guidelines.

Section 3.6 What criteria are used to report an oral fluid specimen as adulterated?

An HHS-certified laboratory reports an oral fluid specimen as adulterated when the presence of an adulterant is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

Section 3.7 What criteria are used to report an invalid result for an oral fluid specimen?

An HHS-certified laboratory reports a primary (A) oral fluid specimen as an invalid result when:

(a) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid immunoassay or alternate technology initial drug test results cannot be obtained);

(b) Interference with the drug confirmatory assay occurs on two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(c) The physical appearance of the specimen (*e.g.,* viscosity) is such that testing the specimen may damage the laboratory's instruments;

(d) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (*e.g.,* color) are clearly different; or

(e) The concentration of a biomarker (*e.g.,* albumin or IgG) is not consistent with that established for human oral fluid for both the initial (first) test and the second test on two separate aliquots.

Subpart D—Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

(b) The immediate supervisor of a federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

Section 4.2 Who may not collect a specimen?

(a) A federal agency employee who is in a testing designated position and subject to the federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work together with that employee on a daily basis.

(b) A federal agency applicant or employee must not collect their own drug testing specimen.

(c) An employee working for an HHS-certified laboratory must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or a close personal friend (*e.g.,* fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to these Guidelines;

(3) Is trained and qualified to use the specific oral fluid collection device. Training must include the following:

(i) All steps necessary to complete an oral fluid collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include two uneventful collection scenarios, one insufficient specimen quantity scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen tube tamper-evident seal.

(ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the trainee, and the trainer must attest in writing that the mock collections are error-free.

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of their training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until the individual's training as a collector has been properly documented.

Section 4.4 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors for a specific oral fluid collection device and may train others to collect oral fluid specimens using that collection device when they have completed the following:

(1) Qualified as a trained collector and regularly conducted oral fluid drug test collections using that collection device for a period of at least one year or

(2) Completed a ''train the trainer'' course given by an organization (*e.g.,* manufacturer, private entity, contractor, federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the trainer's training and provide that documentation to a federal agency when requested.

Section 4.5 What must a federal agency do before a collector is permitted to collect a specimen?

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (*e.g.,* third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the federal agency representative.

Subpart E—Collection Sites

Section 5.1 Where can a collection for a drug test take place?

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (*e.g.,* an accident investigation), another site may be used for the collection, providing the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);

(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;

(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory;

(d) A restricted access area where only authorized personnel may be present during the collection;

(e) A restricted access area for the storage of collection supplies; and

(f) The ability to store records securely.

Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (*e.g.,* collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

(a) A collector must do the following to maintain the security and integrity of a specimen:

(1) Not allow unauthorized personnel to enter the collection area during the collection procedure;

(2) Perform only one donor collection at a time;

(3) Restrict access to collection supplies before, during, and after collection;

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering.

(b) Couriers, express carriers, and postal service personnel are not

required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory.

Section 5.6 What are the privacy requirements when collecting an oral fluid specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F—Federal Drug Testing Custody and Control Form

Section 6.1 What federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used. Based on the documentation provided by the collector, the HHS-certified laboratory must handle and test the specimen as a federal agency specimen.

(c) If the HHS-certified laboratory or MRO discovers that the collector used an incorrect form, the laboratory or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the laboratory reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

Subpart G—Oral Fluid Specimen Collection Devices

Section 7.1 What is used to collect an oral fluid specimen?

An FDA-cleared single-use collection device intended to collect an oral fluid specimen must be used. This collection device must maintain the integrity of such specimens during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites.

Section 7.2 What are the requirements for an oral fluid collection device?

An oral fluid specimen collection device must provide:

(a) An indicator that demonstrates the adequacy of the volume of oral fluid specimen collected;

(b) A sealable, non-leaking container that maintains the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites;

(c) Components that ensure pre-analytical drug and drug metabolite stability; and

(d) Components that do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen.

Section 7.3 What are the minimum performance requirements for a collection device?

An oral fluid collection device must meet the following minimum performance requirements.

(a) Reliable collection of a minimum of 1 mL of undiluted (neat) oral fluid;

(b) If the collection device contains a diluent (or other component, process, or method that modifies the volume of the testable specimen):

(1) The volume of oral fluid collected should be at least 1.0 mL ±10 percent, and

(2) The volume of diluent in the device should be within ±2.5 percent of the diluent target volume;

(c) Stability (recoverable concentrations ≥80 percent of the concentration at the time of collection) of the drugs and/or drug metabolites for five days at room temperature (64–77 °F/18–25 °C) and under the manufacturer's intended shipping and storage conditions; and

(d) Recover ≥80 percent (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff (see Section 3.4).

Subpart H—Oral Fluid Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing an oral fluid specimen?

The following privacy requirements apply when a donor is providing an oral fluid specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor.

Section 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?

The collector must deter the adulteration or substitution of an oral fluid specimen at the collection site.

Section 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?

The collector must take the following steps before beginning an oral fluid specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (*e.g.,* driver's license; employee badge issued by the employer; an alternative photo identification issued by a federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector requests that the donor open the donor's mouth, and the collector inspects the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (*e.g.,* candy, gum, food, tobacco) or could be used to adulterate, substitute, or dilute the specimen. If an item is present that appears to have been brought to the collection site with the intent to adulterate, substitute, or dilute the specimen, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.9.

(1) At this time, the collector starts the 10-minute wait period and proceeds with the steps below before beginning the specimen collection as described in Section 8.5.

(2) If the collector's inspection of the donor's oral cavity reveals any items that could impede or interfere with the collection of an oral fluid specimen (including abnormally colored saliva),

or the donor claims to have ''dry mouth,'' the collector gives the donor water (*e.g.,* up to 4 oz.) to rinse their mouth. The donor may drink the water. The collector must then wait 10 minutes before beginning the specimen collection. If the donor refuses to remove the item or refuses to rinse, this is a refusal to test.

(3) If the donor claims that they have a medical condition that prevents opening their mouth for inspection, the collector follows the procedure in Section 8.6(b)(2).

(e) The collector must provide identification (*e.g.,* employee badge, employee list) if requested by the donor.

(f) The collector explains the basic collection procedure to the donor.

(g) The collector informs the donor that the instructions for completing the Federal Custody and Control Form are located on the back of the Federal CCF or available upon request.

(h) The collector answers any reasonable and appropriate questions the donor may have regarding the collection procedure.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

(a) The collector will provide or the donor may select a specimen collection device that is clean, unused, and wrapped/sealed in original packaging. The specimen collection device will be opened in view of the donor.

(1) Both the donor and the collector must keep the unwrapped collection devices in view at all times until each collection device containing the donor's oral fluid specimen has been sealed and labeled.

(b) The collector reviews with the donor the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(c) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must report a refusal to test in accordance with Section 8.9.

Section 8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the oral fluid specimen:

(a) The collector shall be present and maintain visual contact with the donor during the procedures outlined in this section.

(1) Under the observation of the collector, the donor is responsible for positioning the specimen collection device for collection. The collector must ensure the collection is performed correctly and that the collection device is working properly. If there is a failure to collect the specimen, the collector must begin the process again, beginning with Step 8.4(b), using a new specimen collection device (for both A and B specimens) and notes the failed collection attempt on the Federal CCF. If the donor states that they are unable to provide an oral fluid specimen during the collection process or after multiple failures to collect the specimen, the collector follows the procedure in Section 8.6.

(2) The donor and collector must complete the collection in accordance with the manufacturer instructions for the collection device.

(b) If the donor fails to remain present through the completion of the collection, fails to follow the instructions for the collection device, refuses to begin the collection process after a failure to collect the specimen as required in step (a)(1) above, refuses to provide a split specimen as instructed by the collector, or refuses to provide an alternate specimen as authorized in Section 8.6, the collector stops the collection and reports the refusal to test in accordance with Section 8.9.

Section 8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

(a) If the donor states that they are unable to provide an oral fluid specimen during the collection process, the collector requests that the donor follow the collector instructions and attempt to provide an oral fluid specimen.

(b) The donor demonstrates their inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor a drink (up to 8 ounces) and waits an additional 10 minutes before beginning the specimen collection (a period of 1 hour must be provided or until the donor has provided a sufficient oral fluid specimen). If the donor simply needs more time before attempting to provide an oral fluid specimen, the donor is not required to drink any fluids during the 1 hour wait time. The collector must inform the donor that the donor must remain at the collection site (*i.e.,* in an area designated by the collector) during the wait period.

(2) If the donor states that they are unable to provide an oral fluid specimen, the collector records the reason for not collecting an oral fluid specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

Section 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

Section 8.8 How does the collector prepare the oral fluid specimens?

(a) All federal agency collections are to be split specimen collections.

An oral fluid split specimen collection may be:

(1) Two specimens collected simultaneously with two separate collection devices;

(2) Two specimens collected serially with two separate collection devices. The donor is not allowed to drink or rinse their mouth between the two collections. Collection of the second specimen must begin within two minutes after the completion of the first collection and recorded on the Federal CCF;

(3) Two specimens collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or

(4) A single specimen collected using a single collection device, that is subsequently subdivided into two specimens.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube

A'' and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube B''.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over the cap of each specimen tube. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen tube. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

(e) The collector must ensure that all the information required on the Federal CCF is provided.

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Tube A and Tube B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory that will be testing the Tube A oral fluid specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

Section 8.9 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any oral fluid specimen collected and reports the refusal to test by:

(a) Notifying the federal agency by means (*e.g.,* telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the federal agency's designated representative.

Section 8.10 What are a federal agency's responsibilities for a collection site?

(a) A federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H.

(b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (*e.g.,* virtual, onsite, or self-evaluation).

(c) A federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I—HHS Certification of Laboratories

Section 9.1 Who has the authority to certify laboratories to test oral fluid specimens for federal agencies?

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any HHS-certified laboratory, including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory to send specimens or specimen aliquots to another HHS-certified laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory is prohibited from stating or implying that it is certified by HHS under these Guidelines to test oral fluid specimens for federal agencies unless it holds such certification.

Section 9.2 What is the process for a laboratory to become HHS-certified?

(a) A laboratory seeking HHS certification must:

(1) Submit a completed OMB-approved application form (*i.e.,* the applicant laboratory provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

(2) Have its application reviewed as complete and accepted by HHS;

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for federal agencies.

Section 9.3 What is the process for a laboratory to maintain HHS certification?

(a) To maintain HHS certification, a laboratory must:

(1) Successfully participate in both the maintenance PT and inspection programs (*i.e.,* successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory does not maintain its HHS certification?

(a) A laboratory that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.18, 11.19, and 14.7;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.21 and 11.22 and Subpart P; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS procedures in Subpart P that will be

used for all actions associated with the suspension and/or revocation of HHS-certification.

Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in Section 3.4 and may be sent to the laboratory as undiluted (neat) oral fluid. The PT samples must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff concentration for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be as low as 40 percent of the confirmatory test cutoff concentration when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) for a special purpose.

(2) A PT sample may contain an interfering substance or other substances for special purposes.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) The laboratory must (to the greatest extent possible) handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

Section 9.6 What are the PT requirements for an applicant laboratory?

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, obtain no more than one drug concentration on a PT sample that differs by more than ±50 percent from the appropriate reference or peer group mean over two consecutive PT cycles;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 What are the inspection requirements for an applicant laboratory?

(a) An applicant laboratory is inspected by a team of two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's testing procedures and facilities using an inspection checklist.

Section 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?

(a) An HHS-certified laboratory must undergo an inspection 3 months after becoming certified and at least every 6 months thereafter.

(b) An HHS-certified laboratory is inspected by one or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory must continue to satisfy the minimum requirements as stated in these Guidelines.

Section 9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?

(a) An individual may be selected as an inspector for the Secretary if they satisfy the following criteria:

(1) Has experience and an educational background similar to that required for either a responsible person or a certifying scientist for an HHS-certified laboratory as described in Subpart K;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory.

(b) The Secretary or a federal agency may conduct an inspection at any time.

Section 9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

If an applicant laboratory fails to satisfy the requirements established for the initial certification process, the laboratory must start the certification process from the beginning.

Section 9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

(a) If an HHS-certified laboratory fails to satisfy the minimum requirements for certification, the laboratory is given a period of time (*e.g.,* 5 or 30 working days depending on the nature of the

deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

(b) A laboratory's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

(d) If an HHS-certified laboratory's certification is revoked or suspended in accordance with the process described in Subpart P, the laboratory is not permitted to test federally regulated specimens until the suspension is lifted or the laboratory has successfully completed the certification requirements as a new applicant laboratory.

Section 9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug test results and reports.

(b) The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests (*e.g.,* an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition imposed on the HHS-certified laboratory by a federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the HHS-certified laboratory; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory to ensure fully reliable and accurate drug test results and reports.

(c) The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing.

Section 9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?

(a) When a laboratory's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified laboratory with written notice of the suspension or proposed revocation by facsimile, mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory received the notice, or if expedited review is requested, within 3 days of the date the laboratory received the notice. Subpart P contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any HHS-certified laboratory that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified laboratory that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory that has its HHS certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of Subpart P.

Section 9.16 May a laboratory that had its HHS certification revoked be recertified to test federal agency specimens?

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.15 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory which has had its certification revoked may reapply for HHS certification as an applicant laboratory.

Section 9.17 Where is the list of HHS-certified laboratories published?

(a) The list of HHS-certified laboratories is published monthly in the **Federal Register**. This notice is also available on the internet at *http://www.samhsa.gov/workplace.*

(b) An applicant laboratory is not included on the list.

Subpart J—Blind Samples Submitted by an Agency

Section 10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?

(a) Each federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory that the collector sends employee specimens.

(b) Each federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative and 25 percent must be positive for one or more drugs.

Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier in the selected manufacturer's collection

device as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must be fortified with one or more of the drugs or metabolites listed in Section 3.4.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff concentration.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier in the selected manufacturer's collection device as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

Section 10.3 How is a blind sample submitted to an HHS-certified laboratory?

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the current Federal CCF that the HHS-certified laboratory uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory reports a result for a blind sample that is inconsistent with the expected result (*e.g.,* a laboratory reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory and attempt to determine if the laboratory made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory;

(d) If there is no obvious reason for the inconsistent result, the MRO must notify both the federal agency for which the blind sample was submitted and the Secretary; and

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

Subpart K—Laboratory

Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: Quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (*e.g.,* publications, court testimony,

conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: The candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RP.

Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?

(a) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?

(a) All HHS-certified laboratory staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified laboratory must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

Section 11.7 What security measures must an HHS-certified laboratory maintain?

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (*i.e.,* for the Department, a federal agency, a state, or other accrediting agency) or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.11.

Section 11.10 What must an HHS-certified laboratory do to validate an initial drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 11.11 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following controls:

(1) At least one control certified to contain no drug or drug metabolite;

(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;

(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.12 What are the requirements for a confirmatory drug test?

(a) The analytical method must use mass spectrometric identification [*e.g.,* gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS] or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of an oral fluid specimen when identifying and quantifying drugs or their metabolites.

Section 11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff concentration;

(5) The accuracy (bias) and precision at 40 percent of the cutoff concentration;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.14 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff concentration;

(2) At least one control certified to contain no drug or drug metabolite;

(3) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff; and

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.15 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each invalid or adulterated specimen validity test result must be based on an initial specimen validity test on one aliquot and a confirmatory specimen validity test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results; and

(c) Controls must be analyzed concurrently with specimens.

Section 11.16 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 11.17 What are the requirements for an HHS-certified laboratory to report a test result?

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (e)(1) through (e)(4) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.

(d) For a specimen that has an invalid result for one of the reasons stated in items (e)(1) through (e)(4) below, the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive or adulterated result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(e) A primary (A) oral fluid specimen is reported as an invalid result when:

(1) Interference occurs on the initial drug tests on two separate aliquots (*i.e.,* valid initial drug test results cannot be obtained);

(2) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

(3) The physical appearance of the specimen is such that testing the specimen may damage the laboratory's instruments;

(4) The physical appearances of the A and B specimens are clearly different (note: A is tested); or

(5) The concentration of a biomarker (*e.g.,* albumin or IgG) is not consistent with that established for human oral fluid.

(f) An HHS-certified laboratory shall reject a primary (A) specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not

recovered. The HHS-certified laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(g) An HHS-certified laboratory must report all positive, adulterated, and invalid test results for an oral fluid specimen. For example, a specimen can be positive for a specific drug and adulterated.

(h) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(i) An HHS-certified laboratory must report numerical values of the specimen validity test results that support a specimen that is reported adulterated or invalid (as appropriate).

(j) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(k) HHS-certified laboratories may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(l) HHS-certified laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(m) For positive, adulterated, invalid, and rejected specimens, laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 11.18 How long must an HHS-certified laboratory retain specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, or as an invalid result for a minimum of 1 year.

(b) Retained specimens must be kept in secured frozen storage (-20 °C or less) to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period.

Section 11.19 How long must an HHS-certified laboratory retain records?

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.21) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.20 statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?

(a) HHS-certified laboratories must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, facsimile, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified laboratory name and address;

(3) Federal agency name;

(4) Number of specimen results reported;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test;

(10) Number of specimens reported positive;

(11) Number of specimens reported positive for each drug and drug metabolite;

(12) Number of specimens reported adulterated; and

(13) Number of specimens reported as invalid result.

(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the laboratory is performing drug-testing services.

(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the laboratory.

Section 11.21 What HHS-certified laboratory information is available to a federal agency?

(a) Following a federal agency's receipt of a positive or adulterated drug test report, the federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;

(4) A brief description of the HHS-certified laboratory's initial drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug

(and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.22 What HHS-certified laboratory information is available to a federal employee?

A federal employee who is the subject of a workplace drug test may submit a written request through the MRO and/or the federal agency requesting copies of any records relating to the employee's drug test results or a documentation package as described in Section 11.21(b) and any relevant certification, review, or revocation of certification records. Federal employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines.

Section 11.23 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-certified laboratory must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means an MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the HHS-certified laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

Subpart L—Instrumented Initial Test Facility (IITF)

Section 12.1 May an IITF test oral fluid specimens for a federal agency's workplace drug testing program?

No, only HHS-certified laboratories are authorized to test oral fluid specimens for federal agency workplace drug testing programs in accordance with these Guidelines.

Subpart M—Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

(a) A currently licensed physician who has:

(1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;

(2) Knowledge regarding the pharmacology and toxicology of illicit drugs;

(3) The training necessary to serve as an MRO as set out in Section 13.3;

(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or subspecialty board that has been approved by the Secretary to certify MROs; and

(5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (*e.g.,* answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the internet at *http://www.samhsa.gov/workplace/drug-testing.*

Section 13.3 What training is required before a physician may serve as an MRO?

(a) A physician must receive training that includes a thorough review of the following:

(1) The collection procedures used to collect federal agency specimens;

(2) How to interpret test results reported by HHS-certified IITFs and laboratories (*e.g.,* negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);

(3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;

(4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types; and

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations, review of documentation provided by the donor to support a legitimate medical explanation), and reporting of results specified by any federal agency for which the individual may serve as an MRO;

(b) Certified MROs must complete training on any revisions to these Guidelines prior to their effective date, to continue serving as an MRO for federal agency specimens.

Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and (for urine) substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.17(d) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of 2 years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records

for storage and discard the hardcopy records after 6 months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen, as addressed in Section 8.6.

Section 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

(a) When the HHS-certified laboratory reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory reports multiple results for the primary (A) specimen, as the MRO, you must follow the verification procedures described in 13.5(c) through (f) and:

(1) Report all verified positive and/or refusal to test results to the federal agency.

(2) If an invalid result was reported in conjunction with a positive or adulterated result, do not report the verified invalid result to the federal agency at this time. The MRO reports the verified invalid result(s) for the primary (A) specimen only if the split specimen is tested and reported as a failure to reconfirm as described in Section 14.5(c).

(c) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor provides documentation (*e.g.,* a valid prescription) to support a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency.

(i) Passive exposure to a drug (*e.g.,* exposure to secondhand marijuana smoke) is not a legitimate medical explanation for a positive drug test result.

(ii) Ingestion of food products containing marijuana is not a legitimate medical explanation for a positive drug test result.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency for all drugs except codeine and/or morphine as follows:

(i) For codeine and/or morphine less than 150 ng/mL and no legitimate medical explanation: The MRO must determine if there is clinical evidence of illegal use (in addition to the drug test result) to report a positive result to the agency. If there is no clinical evidence of illegal use, the MRO reports a negative result to the agency. However, this requirement does not apply if the laboratory confirms the presence of 6-acetylmorphine (*i.e.,* the presence of this metabolite is proof of heroin use).

(ii) For codeine and/or morphine equal to or greater than 150 ng/mL and no legitimate medical explanation: The MRO reports a positive result to the agency. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(d) When the HHS-certified laboratory reports an adulterated result for the primary (A) oral fluid specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the federal agency because the oral fluid specimen was adulterated.

(e) When the HHS-certified laboratory reports an invalid result for the primary (A) oral fluid specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result.

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medication), the MRO reports a test cancelled result with the reason for the invalid result and informs the federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a test cancelled result with the reason for the invalid result and directs the agency to collect another specimen from the donor.

(i) If the second specimen collected provides a valid result, the MRO follows the procedures in 13.5(a) through (d).

(ii) If the second specimen collected provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* urine).

(f) When the HHS-certified laboratory reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor.

13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?

(a) When another specimen type (*e.g.,* urine) was collected as authorized by the federal agency, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(b) When the federal agency did not authorize the collection of an alternative specimen, the MRO consults with the federal agency. The federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of oral fluid to complete the test;

(ii) The consequences of the appropriate federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in paragraph (b)(3) of this section and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the federal agency in writing:

(i) A medical condition as defined in paragraph (b)(1) of this section has, or

with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the federal agency.

(ii) A permanent or long-term medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid and is highly likely to prevent the employee from providing a sufficient amount of oral fluid for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the federal agency and recommend that the agency authorize collection of an alternative specimen type (*e.g.,* urine) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has or, with a high degree of probability, could have precluded the employee from providing a sufficient amount of oral fluid. As the MRO, you must report a refusal to test to the federal agency.

(4) When a federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (b)(3)(i) of this section, the agency takes no further action with respect to the donor. When a test is canceled as provided in paragraph (b)(3)(ii) of this section, the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the federal agency plan. The donor remains in the random testing pool.

13.7 What happens when an individual is unable to provide a sufficient amount of oral fluid for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes the donor from providing a sufficient specimen for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the federal agency does not authorize collection of an alternative specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient oral fluid specimen impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* urine) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6 (b)(1)] exists, making provision of a sufficient oral fluid specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*e.g.,* the federal agency is not authorized to allow the donor to begin or resume performing official functions because a negative test is needed for that purpose).

Section 13.8 Who may request a test of a split (B) specimen?

(a) For a positive or adulterated result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that the donor's specimen was reported positive, adulterated, or (for urine) substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or (for urine) substituted result is being reported to the federal agency on the primary (A) specimen.

Section 13.9 How does an MRO report a primary (A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and (for urine) substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

Section 13.10 at types of relationships are prohibited between an MRO and an HHS-certified laboratory?

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with the HHS-certified laboratory that may be construed as a potential conflict of interest.

Subpart N—Split Specimen Tests

Section 14.1 When may a split (B) specimen be tested?

(a) The donor may request, verbally or in writing, through the MRO that the split (B) specimen be tested at a different (*i.e.,* second) HHS-certified oral fluid laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or (for urine) substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must

document in the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) oral fluid specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory available to perform the test), the MRO reports to the federal agency that the test must be cancelled and the reason for the cancellation. The MRO directs the federal agency to ensure the immediate recollection of another oral fluid specimen from the donor, with no notice given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified oral fluid laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or (for urine) substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoff concentrations established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

Section 14.3 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported adulterated?

(a) The HHS-certified laboratory must use its confirmatory specimen validity test at an established limit of quantification (LOQ) to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO.

Section 14.5 What action(s) does an MRO take after receiving the split (B) oral fluid specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) oral fluid specimen as:

(a) *Reconfirmed the drug(s) or adulteration result.* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm a single or all drug positive results and adulterated.* If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm [specify drug(s)] and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm [specify drug(s)] and a refusal to test to the agency and indicates the adulterant that is present in the specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (A) specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(c) *Failed to reconfirm a single or all drug positive results and not adulterated.* The MRO reports to the agency a failed to reconfirm result [specify drug(s)], cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(d) *Failed to reconfirm a single or all drug positive results and invalid result.* The MRO reports to the agency a failed to reconfirm result [specify drug(s) and give the reason for the invalid result], cancels both tests, directs the agency to immediately collect another specimen and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and adulterated.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(f) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not adulterated.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and invalid result.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(h) *Failed to reconfirm adulteration.* The MRO reports to the agency a failed to reconfirm result (specify adulterant) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterant.* The MRO reports to the agency a reconfirmed result (specify adulterant) and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed result (adulterated) although Laboratory B failed to reconfirm the drug(s) result.

(j) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterant.* The MRO reports to the agency a failed to reconfirm result [specify drug(s) and adulterant] and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) *Failed to reconfirm at least one drug and reconfirmed the adulterant.* The MRO reports to the agency a reconfirmed result [specify drug(s) and adulterant] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) and the reconfirmed adulterant although Laboratory B failed to reconfirm one or more drugs.

(l) *Failed to reconfirm at least one drug and failed to reconfirm the adulterant.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s) and adulterant]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to

reconfirm one or more drugs and failed to reconfirm the adulterant.

Section 14.6 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

Section 14.7 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

Subpart O—Criteria for Rejecting a Specimen for Testing

Section 15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the primary (A) or split (B) specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;

(b) The primary (A) specimen label/seal is missing, misapplied, broken or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(c) The collector's printed name and signature are omitted on the Federal CCF;

(d) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen;

(e) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(f) The specimen was received at the HHS-certified laboratory without a CCF;

(g) The CCF was received at the HHS-certified laboratory without a specimen;

(h) The collector performed two separate collections using one CCF; or

(i) The HHS-certified laboratory identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected.

Section 15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the HHS-certified laboratory may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot recover the collector's signature, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-federal form or an expired Federal CCF, the HHS-certified laboratory must test the specimen and also attempt to obtain a memorandum for record explaining why a non-federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot obtain a memorandum for record from the collector, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory should not cause an HHS-certified laboratory to reject an oral fluid specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing at the top of the form;

(2) Incomplete/incorrect/unreadable employer name or address;

(3) MRO name is missing;

(4) Incomplete/incorrect MRO address;

(5) A transposition of numbers in the donor's Social Security Number or employee identification number;

(6) A telephone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A ''reason for test'' box is not marked;

(9) A ''drug tests to be performed'' box is not marked;

(10) A ''specimen collection'' box is not marked;

(11) The lot number of the collection device used for the collection is missing;

(12) The collection site address is missing;

(13) The collector's printed name is missing but the collector's signature is properly recorded;

(14) The time of collection is not indicated;

(15) The date of collection is not indicated;

(16) Incorrect name of delivery service;

(17) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(18) The donor's name inadvertently appears on the HHS-certified laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory should not cause an MRO to cancel a test:

(1) The testing laboratory fails to indicate the correct name and address in the results section when a different laboratory name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print their name;

(3) The certifying scientist or certifying technician fails to print their name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies should occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector or HHS-certified laboratory (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

Section 15.4 What discrepancies may require an MRO to cancel a test?

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported drug positive, adulterated, invalid, or (for urine) substituted; or

(3) The electronic report provided by the HHS-certified laboratory does not contain all the data elements required for the HHS standard laboratory electronic report for a specimen being reported drug positive, adulterated, invalid result, or (for urine) substituted.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If, after at least 5 business days, the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the certifying scientist that they inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory. If, after at least 5 business days, the laboratory does not retransmit a corrected electronic report, the MRO must cancel the test.

Subpart P—Laboratory Suspension/ Revocation Procedures

Section 16.1 When may the HHS certification of a laboratory be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 16.2 What definitions are used for this subpart?

Appellant. Means the HHS-certified laboratory which has been notified of its suspension or proposed revocation of its certification to perform testing and has requested an informal review thereof.

Respondent. Means the person or persons designated by the Secretary in implementing these Guidelines.

Reviewing Official. Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of the official's employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 16.3 Are there any limitations on issues subject to review?

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the relevant Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of these Guidelines shall not be subject to review under these procedures.

Section 16.4 Who represents the parties?

The appellant's request for review shall specify the name, address, and telephone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and telephone number of the respondent's representative.

Section 16.5 When must a request for informal review be submitted?

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 16.6 What is an abeyance agreement?

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period, advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 16.7 What procedures are used to prepare the review file and written argument?

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's Documents and Brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) *Respondent's Documents and Brief.* Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug testing, which is tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply Briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 16.8 When is there an opportunity for oral presentation?

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues, stipulations and admissions, limitations on evidence and witnesses that will be presented at the hearing, time allotted for each witness and the hearing altogether, scheduling the hearing, and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at their discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of the Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date the appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of the official's employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At their discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Section 16.9 Are there expedited procedures for review of immediate suspension?

(a) *Applicability.* When the Secretary notifies an HHS-certified laboratory in writing that its certification to perform drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the HHS-certified laboratory received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official

will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, which is tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7–10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7–10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile, secured electronic transmissions, or overnight mail.

Section 16.10 Are any types of communications prohibited?

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Section 16.11 How are communications transmitted by the reviewing official?

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and federal holidays. However, if a due date falls on a Saturday, Sunday, or federal holiday, then the due date is the next federal working day.

Section 16.12 What are the authority and responsibilities of the reviewing official?

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

Section 16.13 What administrative records are maintained?

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 16.14 What are the requirements for a written decision?

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefore in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue their decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

Section 16.15 Is there a review of the final administrative action?

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under Section 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

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